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surveillance requirements beyond those for CDC reporting (e.g., certain birth defect registries). Information on the proportion of cancer and other health effects that may be associated with environmental exposures would need to be identified to put overall incidence data in the appropriate perspective.

3.5.2 Ecological Effects

Integration of Exposure and Effects Analyses

Risk characterization is the final phase of an ecological risk assessment in which risks are described and estimated by integrating the estimates of exposure and effects developed in the analysis phase. As described in EPA's guidelines (EPA 1998d), and implied in the residual risk decision framework described in Section 5.3, this process requires comparison of the exposure and stressor-response profiles developed during the analysis. In this step exposure concentrations are compared to (1) published background concentrations in media and biota and (2) the levels estimated to cause adverse effects on the assessment endpoints. Generally, there are two ways to quantitatively estimate risks – point estimates and probabilistic estimates – and each has its advantages and disadvantages. One example of a quantitative ecological risk assessment is presented in **Exhibit 18**. Another example is the EPA Region 5 risk assessment for a hazardous waste incinerator in East Liverpool, Ohio (EPA 1997l). Additional case studies of quantitative ecological risk assessments are presented in Paustenbach (1989) and Maughan (1993).

The point estimate approach, which has been used in numerous EPA ecological risk assessments, uses single values (usually upper-bound estimates) to represent key variables in the assessment (Finley and Paustenbach 1994). The approach is relatively simple and straightforward; however, there are several major limitations. The repeated use of upper-bound point estimates can lead to unrealistically conservative risk estimates. In addition, point estimates provide a limited amount of information to the risk manager and the public. Therefore, the point estimate approach is most useful as a screening approach that approximates a plausible, worst case situation for some potentially exposed receptors.

In contrast, the probabilistic approach uses a distribution of data rather than a single point to represent key variables in the assessment (Finley and Paustenbach 1994). This method makes much greater use of the available exposure and toxicity data than the point estimate approach and provides more information to the risk manager. Instead of yielding a single point estimate of risk, the probabilistic approach provides a range of potential risks as well as their likelihood of occurrence. In addition, a probabilistic assessment is more conducive to sensitivity and quantitative uncertainty analysis. Major disadvantages of probabilistic assessments are that they require more time and resources and are more difficult to communicate or “sell” to some stakeholders. Another difficulty is that information on the distribution of input values is often lacking or uncertain.

Residual Risk Report to Congress**EXHIBIT 18****AN ECOLOGICAL RISK ASSESSMENT CASE STUDY: OZONE RISKS TO AGROECOSYSTEMS**

The case study summarized here provides an example of how EPA has assessed environmental risks from an air pollutant (ozone) under the National Ambient Air Quality Standards (NAAQS) program (EPA 1993a; EPA 1996f). In 1997, EPA set a new NAAQS for ozone (EPA 1997m). The new secondary standard was set at a level judged by the Administrator to “provide increased protection against adverse effects to public welfare ...,” including “... against ozone-induced effects on vegetation, such as agricultural crop loss, damage to forests and ecosystems, and visible foliar injury to sensitive species.” This example highlights ecological risk assessment concepts and methods.

- ▶ **Problem Formulation.** Under the CAA, EPA is required to set NAAQS for “any pollutant which, if present in the air, may reasonably be anticipated to endanger public health or welfare and whose presence in the air results from numerous or diverse mobile and/or stationary sources.” EPA develops public health (primary) and welfare (secondary) NAAQS. According to section 302 of the CAA, the term welfare “includes ... effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values ...”. A secondary standard, as defined in section 109(b)(2) of the CAA, must “specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.”

This case study focuses on an assessment endpoint for agricultural crops (e.g., the prevention of an economically adverse reduction in crop yields). Yield loss is defined as an impairment of, or decrease in, the value of the intended use of the plant. This concept includes a decrease in the weight of the marketable plant organ, reduction in aesthetic values, changes in crop quality, and/or occurrence of foliar injury when foliage is the marketable part of the plant. These types of yield loss can be directly measured as changes in crop growth, foliar injury, or productivity, so they also serve as the measures of effect for the assessment.

- ▶ **Exposure Analysis.** The EPA used ambient ozone monitoring data across the U.S. and a Geographic Information System (GIS) model to project national cumulative, seasonal ozone for the maximum three month period during the summer ozone season. This allowed EPA to project ozone concentrations for some rural parts of the country where no monitoring data were available but where crops were grown, and to estimate the attainment of alternative NAAQS scenarios. The USDA’s national crop inventory data were used to identify where ozone-sensitive crop species were being grown and in what quantities. This information allowed the Agency to estimate the extent of exposure of ozone-sensitive species under the different scenarios.
- ▶ **Ecological Effects Analysis.** Stressor-response profiles describing the relationship between ozone and growth and productivity for 15 crop species representative of major production crops in the U.S. (e.g., crops that are economically valuable to the U.S., of regional importance, and representative of a number of crop types) had already been developed from field studies conducted from 1980 to 1986 under the National Crop Loss Assessment Network (NCLAN) program. The NCLAN studies also included secondary stressors (e.g., low soil moisture and co-exposure with other pollutants like sulfur dioxide), which helped EPA interpret the environmental effects data for ozone.
- ▶ **Risk Characterization.** Under the different NAAQS scenarios, the Agency estimated the increased protection from ozone-related effects on vegetation associated with attainment of the different NAAQS scenarios. Monetized estimates of increased protection associated with several alternative standards for economically important crops were also developed. This analysis focused on ozone effects on vegetation since these public welfare effects are of most concern at ozone concentrations typically occurring in the U.S. By affecting commercial crops and natural vegetation, ozone may also indirectly affect natural ecosystem components such as soils, water, animals, and wildlife.

Mixtures. As with non-cancer assessments of human health risks, when ecological toxicity data for complex mixtures are unavailable, the HI approach may be used, as scientifically appropriate, to integrate the ecological risks of multiple chemical stressors (EPA 1996d). HQs for the individual constituents in a mixture are derived by dividing each

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constituent's exposure level by a corresponding criterion for ecological effects. The resulting quotients would then be added together to generate an HI for the mixture for each media/receptor combination (e.g., air/terrestrial animals or water column/aquatic organisms). Use of the HI approach assumes that the toxicities of the mixture constituents are additive or close to additive. This assumption is likely to be true for mixtures of chemicals that have similar modes of action; however, it may be unrealistic to default to a molecular mechanism of toxicity for ecological risk analyses.

Screening-level risk assessment may use the HI approach to estimate the risks of mixtures of HAPs to ecological receptors, but the assumptions and associated limitations concerning HAP interactions should be clearly stated in the assessment's documentation. It may often be the case that a single chemical is responsible for the HI exceeding 1, and the assessment can then move forward with focus on that chemical. In more refined assessments, assumptions inherent in the use of the HI will need to be carefully evaluated with regard to scientific appropriateness.

A major limitation of the HI approach is that it provides a point estimate of the risk and is clearly a one dimensional model that relies on concentration (Suter 1993). Additionally, given the lack of fundamental knowledge of effects at the molecular level for most pollutants, it may be unrealistic to assume a molecular mechanism of toxicity as a means of addressing mixtures of all HAPs. In the future, we may need to consider how chemicals affect critical processes governing fitness of the ecosystem (e.g., photosynthesis in plants, reproduction) in our ecological risk assessments.

Interpretation and Presentation of Risks

The previous discussion on interpretation and presentation of risk in Section 3.5.1 is also applicable with regard to ecological risk characterization. As previously mentioned, the risk characterization phase should include a summary of the strengths, limitations, assumptions, and major uncertainties associated with the risk estimates. Uncertainty analysis in risk assessment is also discussed further in Section 3.5.1 and Section 4.2.3.

As with presentation of human health risks, assessments of environmental risk from air toxics should be presented in context of available information regarding other risks in addition to a summary of the exposure and effects characterizations and their integration. Depending on the problem formulation and analysis plan for the ecological risk assessment, social and economic concerns may need to be incorporated into the more refined assessments. In residual risk management decisions, various other factors must be considered along with the information presented in the characterization of risk of adverse environmental effect. These include "costs, energy, safety, and other relevant factors." These considerations will be documented with the risk management decision.

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Without calibrated or validated population models, professional judgment is needed to estimate the ecological significance of contaminant concentrations that exceed levels associated with varying magnitudes of effect on different species or communities. Unless an endangered or threatened species is at issue, society is generally not concerned with the death of individual plants or animals. For other species, it is unlikely that a few percent additional mortality of individuals could result in population-level effects that might impair ecosystem structure and function. However, it is extremely difficult to estimate how much additional contaminant-induced mortality or reduced reproductive success a population can compensate for before population levels begin to decline, particularly if the population is subject to other stresses. These issues, which should be considered in the development of assessment endpoints in the problem formulation phase, should then be confirmed and described in the risk characterization.

EXAMPLES OF CONSIDERATIONS FOR DETERMINING ECOLOGICAL SIGNIFICANCE

- ▶ How large is the area where ecological criteria have been exceeded?
- ▶ What proportion of the habitat is affected at local, county, State, and national levels?
- ▶ Are the exposure concentrations and ecological criteria above background levels for the area of interest?
- ▶ What types of ecological impacts have been associated with this pollutant or similar pollutants in the past?
- ▶ Is the criterion or stressor-response curve based on high quality data (i.e., is there a high degree of confidence in the criterion)?
- ▶ What are the costs, energy, safety, and other relevant considerations required for decision-making?

Data Availability, Limitations, and Closing Data Gaps

Although our development of tools, data, and methods for ecological risk assessment of air toxics is in its early stages, the Agency has some experience in ecological risk assessment for air toxics (e.g., EPA 1997l) and other air pollutants (see Exhibit 18). A lack of certain types of criteria (e.g., for wildlife inhalation) and of criteria of any type for many of the HAPs may handicap our analyses, especially in the early stages. As part of data development for air toxics assessment, the Agency is in the process of identifying and assessing the available data and data bases for various ecological receptors.

As the Agency refines its tools, there are many issues we will try to address. For example, the issue of chemical residence times in the environment and the scale of ecological analysis is important (e.g., if a chemical has a residence time of a month or more, then the distribution of the chemical can approach hemispheric proportions). Longer residence times in the atmosphere will lead to global distributions and in order to more comprehensively address this issue, risk assessment methods may need the ability to scale appropriately.

4. Other Statutory Report Requirements of Section 112(f)(1)

The preceding chapter describes the methods and general process that will be used for performing human and ecological risk assessment under residual risk and other components of the air toxics program. The general analysis framework that the Agency is currently evaluating for use in the residual risk program is described in Chapter 5. The remaining elements required by statute to be covered in the section 112(f)(1) Report to Congress are addressed in this chapter. Additional aspects of some of these topics are also covered in other parts of this Report.

4.1 Section 112 (f)(1)(B)

Section 112(f)(1)(B) of the Clean Air Act directs EPA to investigate and report on “the public health significance of such estimated remaining risk and the technologically and commercially available methods and costs of reducing such risks.” These topics are presented in the following two sections.

4.1.1 Public Health Significance

This section addresses the directive in CAA section 112(f)(1)(B) that EPA investigate and report on “the public health significance of such estimated remaining risk.” At present, the data are not available to conduct an analysis to determine the public health significance for residual risk from air toxics. Given the legislatively mandated schedules for MACT implementation and for performing residual risk assessments, analyses have not yet been completed on any source categories for the purposes of estimating potential residual risks. Without these analyses, it is not possible to determine at this time what the public health significance of any residual risks may be.

As residual risk assessments are completed for individual source categories, information relevant to public health context, as available, will be presented in the risk characterization step (see Section 3.5.1) of the final analysis. This information will include, for each source category or source, the estimated risks to public health remaining after MACT is in place, health effect information, and the attendant uncertainties. Additional available public health information relevant to the risks predicted may also be presented. For example, in the case of estimates of cancer risk, available relevant information on cancer incidence or prevalence may be presented with whatever specificity (e.g., cancer type relevant to HAP cancer hazard information, geographic unit relevant to the source or source category) is feasible. Estimates of non-cancer risk may be presented with a discussion of the health effects of concern and presentation of readily available information regarding prevalence of those health effects, as appropriate. The Agency recognizes, however, that availability of information on the health status of populations, especially on a local basis, is currently quite limited. While this is improving in some areas, such as in states that maintain cancer registries in accordance with National Cancer Institute

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specifications, among the general population there are many other health effects for which HAPs pose potential risks that are not well tracked.

The available public health information will be considered along with estimated risks and uncertainties in the application of the ample margin of safety framework as part of the decision-making process of the risk management step (Section 5.3.6).

The Agency considers the ample margin of safety concept as introduced in the 1970 CAA Amendments, and as applied in the benzene standard (EPA 1989a), a reasonable approach to evaluate public health significance and to manage residual risks under CAA section 112. Such an approach is consistent with the Congressional language in section 112(f)(2) (see Appendix A). The 1989 benzene NESHAP presented a structure for applying ample margin of safety to setting standards for carcinogens. This two-step structure included an analytical first step to determine an “acceptable risk” after considering all health information, including risk estimation uncertainty. In the case of benzene, a linear carcinogen, this included a presumptive limit on maximum individual lifetime cancer risk of approximately 1 in 10 thousand. In the second step, the standard is set at a level that provides an ample margin of safety in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other factors such as costs and economic impacts, technological feasibility, and factors relevant to the particular decision.

4.1.2 Available Methods and Costs of Reducing Residual Risks

Section 112(f)(1)(B) of the CAA directs EPA to investigate and report on “the technologically and commercially available methods and costs of reducing [residual] risks” from HAPs. This section of the Report provides a broad characterization of post-MACT emissions, an overview of control strategies, and a discussion of key factors that will influence the available methods and costs.

Two general types of strategies can be used to reduce the human health and environmental risk associated with HAP exposure. One is to limit releases into the atmosphere. These “pre-release” strategies employ various control technologies and pollution prevention methods developed by industry to comply with regulations requiring them to reduce HAP emissions. A second approach, applicable primarily to protecting public health, is through the adoption of “post-release” strategies to keep people out of HAP exposure pathways – that is, to eliminate or minimize contact between people and HAP-contaminated media. Measures of this type can include institutional and regulatory approaches such as zoning controls and advisories, which limit public access to areas that contain unhealthful HAP concentrations, fishing restrictions and fish consumption advisories, and provision of alternate drinking water supplies. These strategies are used most often in cases where unregulated sources already have emitted large quantities of pollutants, or as emergency response measures to protect the public from pollution caused by accidents or spills.

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Pre-release strategies have traditionally been the preferred method to protect the public from exposure to harmful pollutants because they minimize the impact on the environment and place the burden of managing wastes on the source itself. Pre-release methods are consistent with our environmental management philosophy of encouraging pollution prevention/recycling/treatment first, and pollution disposal/release only as a last resort. Hence, this section focuses on the technologically and commercially available pre-release strategies that can be used to reduce residual risk.

Given the site-specific and HAP-specific nature of control technology and cost determinations, combined with the fact that there are 188 HAPs and more than 170 source categories and that no post-MACT risk assessments for source categories have been completed, an in-depth discussion of the specific methods and costs of controlling post-MACT HAP emissions is beyond the scope of this Report. Instead, the remainder of this section presents a brief review of some of the emissions control strategies employed under the MACT requirements and discusses how these strategies will influence the available options for further reducing the risks of HAP emissions to the general public. A discussion of general MACT requirements is followed by an overview of currently available control strategies, with an emphasis on ways that industries can go beyond the requirements of MACT and other existing air regulations. Topics addressed include site-specific parameters needed to select appropriate controls for a specific facility and available options for reducing emissions, including add-on control equipment, process/work practice modifications, pollution prevention techniques, and voluntary/incentive based programs that encourage facilities to further reduce HAP emissions. Finally, a general discussion of the key factors that influence the costs of these various strategies is provided.

MACT Emission Standards

MACT emission standards typically require one or more of the following control requirements in order to reduce emissions: meeting a numerical or percent efficiency control target, or a design, equipment, work practice, or operational standard. For several MACT emission standards finalized as of October 1996, Tables I through IV of Appendix E summarize the control standard established for several types of emission sources (i.e., process vents, equipments leaks, coating operations, and solvent cleaning operations). The percent or level of control established in a MACT standard usually represents a certain type(s) of control technology. For example, the 98 percent control level shown in Table I for process vents usually translates to the use of thermal incineration as the control technology. However, the selection and exact specification of controls is a site-specific determination, as discussed further in the section below entitled "Available Control Strategies."

The MACT determinations, like other broadly applicable emissions control standards, are based on decisions about the most effective, feasible, and reliable controls available. However, MACT standards in a particular source category do not necessarily represent the most stringent state-of-the-art controls available to that industry. Cost and other considerations may result in

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the most stringent controls not being selected as the national MACT standard. This is because the CAA states that MACT standards for existing sources:

“ . . . shall require the maximum degree of reduction in emissions of the hazardous air pollutants... that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts...determines is achievable . . .”

Accordingly, controls capable of achieving greater HAP reductions may have been ruled out at the time of the MACT determination because of cost or other considerations. However, such costs may later be determined to be reasonable if analysis indicates significant residual risks. It is also possible that, over time, market conditions or technological improvements in certain control technologies could reduce the cost of currently expensive controls to less expensive levels, making their adoption more feasible.

Available Control Strategies

The most effective and feasible HAP control technology for a particular application must be determined on a case-by-case basis after careful consideration of many site-specific issues, such as the design of the facility, the overall manufacturing process, the chemicals being used, the emission stream characteristics, the desired control efficiency, and the cost-effectiveness of the various control options. Even within a particular industry, the methods used to control a specific type of HAP from a certain industrial process will vary from facility to facility. Because of this considerable variation in the types of controls used, a detailed discussion of specific strategies is beyond the scope of this Report. Instead, a review of the general types of methods available for control of post-MACT emissions is provided.

For the purpose of evaluating available control strategies, it is likely that emissions from source categories regulated by MACT emission standards will fall into two basic types:

- (1) *Controlled* sources, which are emission sources where some degree of reduction has already taken place; or
- (2) *Uncontrolled* sources, which are emission sources that emit directly to the atmosphere without constraints.

For both types of emission sources, a MACT determination was made to require either add-on controls or implementation of a work practice or an operational restriction, or not to require controls. Residual (post-MACT) emissions are emissions associated with both controlled and uncontrolled sources within the source category.

Residual emissions from controlled sources are generally streams of low HAP concentration because the original emission stream has already been subjected to a MACT level

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of control. As a result, the range of available control strategies for further reductions from these low concentration streams is limited, especially for emission streams already controlled to 90 percent or higher.

Residual emissions from uncontrolled sources may range from low to high HAP concentration, but generally are of a lower magnitude of emissions than emissions from the sources subject to some level of control. Accordingly, controls capable of reducing HAP emissions from uncontrolled streams may exist, but at the time of the MACT determination there may have been no MACT floor, and controlling above the MACT floor may have been ruled out because of cost or other considerations. However, costs may later be determined to be reasonable if residual emissions are determined to present significant residual risks.

Potentially effective strategies for controlling HAP emissions – some of which will be applicable to further controlling sources already subject to MACT – include:

- Pollution prevention (P2) techniques, such as replacing hazardous substances with less harmful substitutes;
- Adding a technological control, either to a previously uncontrolled source or as a supplement to existing controls;
- Replacing existing controls with a more effective control technology; and
- Changing work practices.

Methods range from the complex and costly (e.g., redesigning the manufacturing process or retrofitting stacks with sophisticated technological controls) to less costly P2 approaches (e.g., substituting less toxic alternatives for hazardous substances or modifying work practices to reduce emissions). Facilities can be further encouraged to reduce HAP emissions through the use of voluntary/incentive based programs. This range of control options is discussed further below.

Add-on Controls. Different add-on control technologies are required for point and fugitive emission sources. Fugitive source emissions can be captured with hoods, enclosures, or closed vent systems and then transferred to a control device, such as those noted below. Improved equipment (e.g., pumps, valves, seals) may also be used to prevent fugitive HAP emissions. Different add-on technologies are used to control emissions of organic vapor, inorganic vapor, and particulate HAPs. Add-on devices used to control organic vapor emissions include combustion devices (i.e., thermal incinerators, catalytic incinerators, flares, boilers, and process heaters) and recovery devices (i.e., condensers and absorbers). The two most common methods available for controlling inorganic vapor emissions are absorption (scrubbing) and adsorption. A third technique, combustion, may be used for some inorganic HAPs (e.g., carbonyl sulfide). The three types of devices typically used to control particulate HAP emissions are fabric filters (baghouses), electrostatic precipitators, and venturi scrubbers. The applicability of each device depends on the physical and/or chemical/electrical properties of the HAP particle

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under consideration in addition to the specific gas stream characteristics and parameters. Table V of Appendix E provides a summary of typical control devices currently used to reduce emissions from some source categories.

Process/Work Practice Modifications. Process modification refers to any strategy that seeks to reduce emissions by changing the operating practices of the facility or making internal equipment changes. Examples include the re-design of a system to recover and recycle the emissions stream. Some firms choose to make internal equipment changes by implementing cleaner processing technologies through equipment modifications and modernization. Many of these strategies overlap with the P2 tactics that are being used with increasing frequency by industry (discussed below). Operating practice changes include re-designing industrial processes to be more efficient, or instituting alternative work practices to reduce emissions. Work practice changes may include a wide variety of activities such as changing the ways that employees apply industrial solvents or reducing the amount of solvents used and allowed to evaporate. Also, where workers are directly involved in a manufacturing process there may be ways to change worker practices to reduce HAP emissions. Another example is increasing maintenance of process equipment. Implementing a leak monitoring program to detect and repair leaking components is an effective work practice to reduce fugitive emissions.

Pollution Prevention. Pollution prevention is the term used to describe a set of control strategies designed to minimize waste generation through cleaner production. The Pollution Prevention Act of 1990 defines P2 as any source reduction practice that “reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal.” The potential benefits of P2 strategies include improving plant efficiency, saving money, and enhancing the quality and quantity of natural resources for production. In addition, P2 can be more cost-effective than traditional add-on HAP controls. While there is much discussion and debate about what exactly constitutes P2, the following general characteristics are typical:

- Reduction of substance volumes;
- Substitution for toxic substances;
- Implementation of clean technology; and
- Installation of in-process recovery equipment (recycling).

Reducing the amount of toxic chemicals used in the production process generally results in cleaner production and the generation of less waste, including HAPs. Product substitution involves replacing hazardous substances used in the production process with alternatives that result in lower hazardous substance emissions. A common example is the replacement of VOC-laden solvents and lubricants with water based formulations. Many hazardous chemicals used in manufacturing have environmentally safe substitutes that can be used in their place. In some cases there may be effectiveness and cost trade-offs to using an alternative product, but for many

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industrial substances cost-effective alternatives exist. Ultimately, each of these P2 programs reduces the amount of wastes that is generated in the production process. Because the combustion of industrial wastes is a major source of HAP emissions, designing facilities to produce less waste will result in direct air quality benefits.

Voluntary and Incentive Based Approaches. More industries than ever before are voluntarily controlling emissions. This is due in part to the many federal pollution prevention programs that have been established to encourage self-regulation by industry, as well as to liability considerations, community pressures, and the desire to be a “good citizen.” For several years EPA has been experimenting with voluntary partnerships between government and industry as a means to more rapidly achieve environmental goals. The Agency’s 33/50, Energy Star, Green Lights, and Green Chemistry programs have succeeded in gaining commitments from thousands of industrial sources to reduce air emissions, including HAPs. Industries have responded positively to these programs because of their voluntary nature and the positive public recognition they receive for participation. Their success in achieving environmental results demonstrates that voluntary programs can be an effective way to encourage companies to adopt control strategies for reducing HAP emissions and residual risks.

Incentive based policies may be another way to reduce the total HAP emissions released into the atmosphere beyond currently mandated MACT levels. These policies allow sources the flexibility not only to choose what technologies to use for their reductions, but how extensive their reductions will be.

Control Strategy Cost

Just as specific control technologies cannot be examined until the specific source category and HAP or HAPs have been identified, the specific cost to reduce any residual risk that may remain following MACT implementation cannot be determined at this time. Cost analyses are critically dependent on numerous and various conditions, including individual source stream characteristics, HAP characteristics, site conditions at a particular facility, level of control necessary, and the various control options that may be considered. After MACT has been promulgated and a source category and particular HAP (or HAPs) have been identified for residual risk reduction, a detailed cost analysis can be performed.

Factors that may be considered in assessing the cost-effectiveness of a particular control strategy include:

- Capital costs (e.g., the cost of the equipment, estimated costs for site preparation and installation, and cost of ancillary modifications and upgrades to monitoring and process control equipment);
- Cost of capital for the affected industry;
- Fuel costs;

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- Chemical costs;
- Incremental labor costs to operate equipment;
- Production penalties associated with the equipment, and other opportunity costs;
- Control efficiency for various streams;
- Expected performance degradation over the life of the equipment;
- Expected equipment life;
- Lost producer surplus; and
- Lost consumer surplus.

With this information, capital costs can be annualized; operating costs can be disaggregated into fixed and variable costs; life cycle, annual emission estimates can be derived; and costs and emission reductions can be estimated for a variety of operating scenarios. These data are typically entered into an existing model, such as the EPA model HAP-PRO, to determine control cost-effectiveness in terms of cost per mass of pollutant reduced.

4.2 Section 112(f)(1)(C)**4.2.1 Epidemiological and Other Health Studies**

Section 112(f)(1)(C) requires EPA to assess and report on "the actual health effects with respect to persons living in the vicinity of sources, any available epidemiological or other health studies . . ." Information on actual health effects on neighboring populations resulting from HAP emissions from source categories is limited. This section presents a summary discussion of epidemiological, laboratory, and other exposure studies, then briefly describes how EPA intends to use these data and actual source category-specific health effects data that may become available in the context of section 112(f) residual risk assessments.

Current State of Knowledge

The earliest efforts to investigate the relationship between air pollution and ill health were focused on characterizing the relationship between obvious and acute effects (respiratory irritation, exacerbation of asthma, other respiratory and cardiovascular disease and death) and short-duration incidents ("air pollution episodes") of high exposures to combustion products. In extreme cases (such as the episodes occurring in Donora, Pennsylvania in 1948 and London, England in 1952) noticeable increases in acute mortality have been seen. In less serious episodes, increased incidence of respiratory diseases often occurs. Beginning in the late 1980s, studies of adverse health effects near hazardous waste disposal sites began to appear, including U.S. studies such as those conducted by the Agency for Toxic Substances and Disease Registry (ATSDR) (Dayal et al. 1995), as well as a number of foreign studies (Klemans et al. 1995). While it has been reported that individuals who live or work in the vicinity of sources of air toxics emissions were, in some cases, found to have higher exposures than the general population (EPA 1995g), most health effects studies, generally, do not focus on populations near sources of

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HAPs. Therefore, information on potential health effects of air toxics is primarily based on laboratory animal and occupational studies. These types of studies are suggestive of potential adverse effects, but usually evaluate chemicals at higher exposures than normally expected for the general human population. Human epidemiological data can give evidence of potential effects, but are often limited by lack of actual exposure conditions, lack of statistical power, or confounding factors.

Besides laboratory and occupational studies to assess health effects, investigators have employed techniques such as follow-up studies of geographic patterns of disease (particularly cancer), emissions inventories, exposure and risk assessment studies, and biomarker studies of selected pollutants (see accompanying text box). These studies generally have focused on the following major types of health effects – cancer, respiratory irritation and other respiratory toxicity, neurobehavioral toxicity, hepatic effects, renal effects, and reproductive and developmental effects – attributed to air pollutants, and investigators have evaluated associations between exposures and health effects. For example, epidemiologic studies of air toxics have focused on the cancer endpoint because (1) there are established and easily accessible data bases of cancer mortality and, to a lesser extent, incidence at national and regional levels, and (2) many toxic air pollutants are suspect or confirmed human carcinogens. Some of these carcinogenic pollutants also are convenient subjects for environmental studies because they are persistent in air and soil-water systems, and exposures can thus be more readily measured and estimated.

Focused studies of particular classes of toxic air pollutant sources to assess effects of adverse exposures have also been performed. Initially, attention was given to the well-studied and common metallic pollutants such as cadmium and lead, other criteria pollutants, or other general indicators of air quality. Some of the toxic metals represent special cases, each having its own unique pattern of non-cancer effects. The renal effects of cadmium exposures (ATSDR 1993a), neurodevelopmental impacts of lead (ATSDR 1993b), and reproductive toxicity of mercury exposures (ATSDR 1994) are the most well-studied examples. In addition, a few studies use total mortality, or cause specific mortality, as endpoints. Individually, these various studies have provided data that contribute to an understanding of the relationship between air pollution exposure and adverse effects, on both the qualitative and quantitative level.

The Agency has recently surveyed the published literature on the actual human health effects of outdoor air toxics exposures at ambient levels (EPA 1995g), and some information from this study is summarized in this section and provides examples of the difficulties inherent in making causal connections between exposure and effects. One of the most extensively investigated connections between exposure to air pollutants and health effects is that between lung cancer and exposure of populations near smelters to arsenic. Several studies have addressed this relationship (Brown et al. 1984; Frost et al. 1987; Pershagen 1985). These studies tend to show increased risk associated with exposure (or exposure surrogates, such as distance from the smelter), although the apparent increase was not statistically significant in all cases. For example, Frost et al. (1987) found that lung cancer patients were more likely to live close to an

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**SOME APPROACHES TO ESTABLISH RELATIONSHIP
BETWEEN AIR TOXICS EXPOSURE AND HEALTH EFFECTS**

- ▶ **Laboratory Studies.** Adverse health effects of exposures to specific pollutants are often evaluated in studies with laboratory animals or human volunteers. In these studies, the pollutant concentrations are likely to be higher than the exposures to the general population, and with animal studies, extrapolation of the observed effects to humans must be considered.
- ▶ **Studies of Geographic Patterns of Disease Incidence or Mortality.** Studies of vital statistics, disease incidence, or mortality may disclose geographic patterns of adverse health effects that are suggestive of a relationship to specific pollutants or pollutant sources. If such studies are not supplemented by exposure data, and are not controlled for confounding factors other than pollutant exposures, it is not possible to support inferences of causation associated with pollutant exposures.
- ▶ **Studies of General Population Exposures, Exposure Indices, and Biomarkers.** These types of studies have been used to estimate human exposures to pollutants and draw inferences about potential adverse effects. The collected information is often used, in conjunction with toxicity data, to conduct risk assessments. In some instances, measurable indices of exposures (biomarkers of exposures), such as body burdens or tissue concentrations of pollutants, can be used to document exposures and evaluate the potential for adverse effects.
- ▶ **Occupational Exposure/Epidemiology Studies.** Health effects of specific pollutants are often first discovered through observations of adverse effects in workers exposed to high levels of the pollutants. These studies, however, do not directly address the potential for adverse effects occurring in the general population at lower exposure levels.
- ▶ **Formal Environmental Epidemiology Investigations.** A "formal" environmental epidemiology study involves systematic investigation of the relationship between an observed pattern of adverse health effects and exposures to one or more agents. The analysis of actual (as opposed to estimated) health outcome information is what distinguishes an epidemiological study from a risk assessment or a biomarkers study. Systematic efforts to control for confounding factors (factors other than exposures to the toxic substances of interest which may be responsible for the observed effects) are what distinguish a formal ("analytical") epidemiologic study from a simple "descriptive" summary of geographic patterns of disease incidence. Often, formal epidemiologic studies are not a powerful enough tool to discern relatively small increases in disease.
- ▶ **Risk Assessments.** In a risk assessment, information about exposures (which may reflect actual measured exposures or exposures estimated using emissions and environmental models) is combined with toxicity information (from occupational or laboratory studies) to develop predictive estimates of the frequency or severity of occurrence of adverse effects in human populations. There is a high degree of uncertainty due to imprecision in exposure estimates and uncertainties in dose-response information, especially at low doses.

arsenic-emitting smelter (borderline statistical significance) in a case control study that was conducted with women to reduce confounding from occupational exposure. However, there was no control for smoking and no effect was seen in the cross-sectional phase of their study. Pershagen (1985) analyzed lung cancer data near an arsenic-emitting smelter, with the data stratified by smoking status and occupational exposure. In the group that was not occupationally exposed, there was an increased relative risk with proximity to the smelter for both nonsmokers and smokers, but the increase reached statistical significance only among the smokers. Hughes et al. (1988) reviewed more than 10 studies investigating health effects (primarily lung cancer) in communities near arsenic-emitting industries. They noted that about half of the studies reported significant increases in adverse effects while about half of them reported no effect or decreased

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risk in the exposed populations. However, these authors noted that many of the studies (particularly those that observed no statistically significant effect) lacked sufficient statistical power to detect the small increases in risk that would be expected, and suggested that some small increase in risk is likely.

With respect to other effects, Nordstrom et al. (1978) found decreased birth weight in babies born to mothers who lived close to an arsenic-emitting smelter. However, it is unclear if the magnitude of the decrease was clinically significant (Hughes et al. 1988).

Several studies have attempted to show an association between vinyl chloride emissions and central nervous system birth defects (Edmonds et al. 1978; Rosenman et al. 1989; Theriault et al. 1983). While all of these studies reported some association between potential exposure and disease, each was limited by uncertainties in the exposure estimates, implausible results, or potential confounding factors such as smoking or drinking. Overall, these studies provide insufficient data to conclude that there is a causal relationship between ambient air exposure to vinyl chloride and central nervous system birth defects.

An overall view of the epidemiologic literature on exposure to air toxics in the environment is consistent with the notion that concern is warranted. However, understanding of the risks to individuals living near sources and exposed daily to these air toxics is limited or confounded by other factors. Except for a few well-known cases (the sudden release of a large volume of methyl isocyanate in Bhopal, India, for example) where extremely high exposures to accidental releases of industrial chemicals resulted in severe acute health effects, the adverse effects of exposures to airborne hazardous chemicals are generally very difficult to detect.

Because of the difficulties in the extent and usability of epidemiology data, EPA has looked into other types of data that may help bridge the gap between cause and effect. In this context, the state-of-the-art in exposure monitoring and the use of biomarkers has become an expanding field of research. For example, the existing literature on neurobehavioral effects of toxic air pollutants is dominated by discussions of the adverse effects of lead on intellectual and behavioral indices in children. These studies generally describe decrements in performance as a function of biomarkers of lead exposure, such as blood lead concentrations or heme metabolite levels. There is, however, little information available from these studies on the sources of lead exposures, and lead from deteriorating paint and in pipes and solders used for drinking water distribution can contribute significantly to total exposures.

In a study by Binkova et al. (1995), PAH DNA adducts were measured in a group of women in the Czech Republic who worked outdoors for about eight hours per day. Personal exposure monitoring was used, allowing both indoor and outdoor exposure to PAHs to be evaluated; exposure to respirable particles ($<2.5 \mu\text{m}$) and PAHs was measured. Levels of DNA adducts in white blood cells were increased immediately after days of high PAH exposure. This study demonstrated that DNA adducts can be used as biomarkers of exposure, reflecting short-term exposure levels. In addition, DNA adducts can be used as biomarkers of effect, because, if unrepaired, they can lead to gene mutations, which in some cases can ultimately lead to cancer.

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However, due to the multiple steps from gene mutation to cancerous cell, DNA adducts and gene mutations are best viewed as indicating carcinogenic potential rather than indicating actual risk of cancer.

Blood or tissue concentrations of metals such as cadmium are also occasionally used as indicators of exposure and potential adverse effects for airborne toxics. Among the studies that use biomarkers of exposure are evaluations of tissue, hair, and urine cadmium levels in a population near heavily industrialized cities in Russia (Busteva et al. 1994). Urinary cadmium is a reliable indicator of recent cadmium exposure, as shown by several occupational studies. The presence of the protein β -2-microglobulin in urine (termed proteinuria) is also considered a reliable indicator of cadmium exposure. Busteva et al. (1994) reported that the percentage of factory workers having elevated levels of this protein in their urine (>250 ug/l) was highly correlated with the air content of cadmium. Although no significant effect was seen in the general population, this may have been due to the small sample size and resulting low statistical power. Collecting biological samples and conducting laboratory testing, as in this study, is more labor-intensive than doing epidemiological investigations using disease registries. However, because proteinuria is a well-characterized effect of cadmium exposure, and both exposure and effect biomarkers can be monitored by urinalysis, this technique has applicability where high exposure to cadmium is expected.

Another potential source of information may be nationally standardized and comprehensive disease registries or data bases for adverse effects of toxics exposures, such as birth defects and reproductive outcomes (Shy 1993), but again, there are limitations in its use. Currently, studies that use these sources require investigators to obtain access to local or State health status information, whose availability is highly variable from State to State, or to obtain information from hospital or other medical records where confidentiality may become an issue. This difficulty is less of a concern for case control studies, but can severely limit the ability to do large-population cohort analyses or cross-sectional studies.

Acute effects such as seen in occupational settings are less likely to be seen in studies of the general population exposed to toxic air pollutants at ambient levels, with the possible exception of chemicals that have specific irritant properties. In addition, the effects of usually low chronic exposures to toxic air pollutants may be subtle, and may develop slowly over time in response to cumulative exposures (chronic effects), or may not develop until long after exposures occur (latent effects). Information on exposure levels to toxic air pollutants near sources, as well as to "background" pollutants that may be confounding the results of air pollutant epidemiology studies, is also generally limited. Thus, it is not easy to directly estimate the risks associated with general population exposures to toxic air pollutants under conditions of chronic low-level exposures. Nonetheless, it is currently assumed for prudent public health reasons that such effects may be occurring because, for example, many toxic air pollutants are suspected or known human carcinogens and even low levels of exposure could theoretically cause increased cancer risks. In a smaller number of cases, animal or controlled human studies indicate that noncarcinogenic effects might be expected to occur at exposures near ambient levels. In some instances, allergic sensitization may result in adverse effects in a small, especially sensitive

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subset of the exposed population. There is presently no national monitoring system for air toxics that can provide even general information on the urban and rural concentration patterns of these pollutants in ambient air.

Other issues to consider in trying to assess the actual health effects of air toxics include (1) the lack of indoor exposure data and (2) the often observed coincidence between exposures to toxic air pollutants and exposures to criteria air pollutants. Information on indoor exposure data is useful since the majority of individuals spend most of their time (usually 80 percent or more) indoors. Because concentrations of some air toxics in indoor air tend to be quite different from (and often higher than) those outdoors, studies which do not take indoor air quality into account will have difficulty in elucidating the true relationship between these air toxics exposures and effects. Both toxic air pollutants and criteria pollutants are associated with areas of high population density and industrial development, and many epidemiologic studies simply use measures of one or a few criteria pollutants as the sole measure of exposure, and use it as a proxy for all "air pollution." For example, in many studies that assess the relationship between particulate exposures and acute and chronic health effects (usually where there is no clearly identified dominant source of particulate air pollutants), it is not known which chemical or physical constituents of particulates contribute to the observed increases in risk, and it is therefore not possible to attribute any given fraction of these effects to toxic air pollutants.

Strategy for Considering Epidemiology/Other Health Information in Residual Risk Analyses

Early in the data gathering stage of a residual risk analysis, the Agency will search the scientific literature for published epidemiological studies related to the specific source categories, HAPs, and/or locations studied. These reports will be evaluated for quality, with preference given to those covering emissions from the source categories of concern at environmentally relevant concentrations over long periods. Where published epidemiological studies are unavailable, the Agency may also consider, as part of its refined analysis, examining other types of available human health data for possible correlations between exposure and adverse effects. Potential sources of health effects information include State or national disease registries (e.g., the Centers for Disease Control's Birth Defects Monitoring data base), hospital and other medical records, death certificates, and questionnaires. The EPA intends to coordinate the identification, collection, and review of such data with the Public Health Service and other federal, State, and local public health officials. Examples of widely reported outcomes include cancer incidence or mortality, birth defects, and respiratory symptoms. Information on pollutant specific biomarkers – biological measurements associated with exposure to certain pollutants – may also be available. Exposure to HAPs may be estimated in several ways, including ambient monitors, mathematical modeling, or personal air monitors. The Agency recognizes the difficulties that exist in obtaining actual health effects data. However, EPA believes that it may be useful to incorporate some kinds of health effects/epidemiology data in the residual risk assessments for selected air pollutants and source categories and intend to use existing data wherever scientifically appropriate. The Agency will consider any such available public health information in the risk characterization step, and will present and discuss the risk estimates in the

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context of such information. Clearly, any actual health effects data can generally only be used to help establish current or past conditions, and cannot be used directly in the prediction of post-MACT risks that may occur in the future (i.e., residual risks).

4.2.2 Risks Posed by Background Concentrations

Section 112(f)(1)(C) also requires EPA to assess and report on "risks presented by background concentrations of hazardous air pollutants . . ." This section of the Report discusses general information on background levels and presents a definition of background concentrations for residual risk purposes. It describes approaches used by other EPA programs and includes examples of rules and guidance that consider the issue of background. It also presents a discussion of the difficulties in addressing background concentrations in residual risk analyses and identifies data needs to assess background. The section concludes by describing options to analyze and consider background concentrations in residual risk analyses. It describes how EPA will assess available monitoring data for individual source categories under study, and how background concentrations will be evaluated in residual risk assessments and treated in decision-making.

Background concentrations may be considered to be the levels of contaminants that would be present in the absence of contaminant releases from the source(s) under evaluation. Background concentrations come from contaminants that either may occur naturally in the environment or originate from anthropogenic sources. Background contamination can be localized or ubiquitous. An example of localized contamination is the presence of high concentrations of trace metals in dust from geologic formations naturally high in trace metals. An example of ubiquitous contamination is the widespread presence of low concentrations of polyaromatic hydrocarbons in soil and dust in areas near forest fires.

The EPA's Science Policy Council is developing a cumulative risk policy with the goal of developing a framework for conducting cumulative risk assessments. While Part 1 of the *Guidance on Cumulative Risk Assessment* released in August 1997 (EPA 1997n) does not provide an explicit definition of cumulative risk or background, in general cumulative risk is considered to include risks from multiple sources, pathways, and pollutants. The cumulative risk guidance identifies elements that must be considered in a cumulative risk assessment such as the cumulative effects of mixtures on different and the same target organs from multiple sources by direct and multipathway exposures. Cumulative risk is therefore broader than the "incremental

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risk" (or "excess risk") attributable to a given source/pathway/pollutant combination under evaluation.

The general approach in risk assessments and risk management decisions has been to assess incremental risk of a particular source or activity and compare that risk to an "acceptable risk" criterion (or set of criteria). Various EPA programs, however, have taken specific approaches to considering background risks, some of which are summarized below.

EPA Programs and Rules that Consider Background Concentrations and Risks

Site risk assessments under Superfund and the RCRA corrective action program require the collection of background samples at or near hazardous waste sites in areas not influenced by site contamination, but that have the same basic characteristics as the medium of concern. Generally, comparison of background and source-related contamination is used to identify areas affected by the source and contaminants attributable to the source. Incremental risks are then assessed for contaminants in media demonstrated by comparison with background concentrations to have originated from the source. The level of risk reduction is generally set by cleanup levels based on achieving an acceptable risk or reducing contaminants to background concentrations, whichever is least stringent. However, in some cases where anthropogenic background levels exceed cleanup goals, EPA may determine that a response action under Superfund is necessary and feasible, and a comprehensive plan may be developed to address area-wide contaminated media not originating from the site source. In such cases, reduction of anthropogenic background risks becomes an additional goal of the remediation program.

In 1993, EPA's Office of Wastewater Management developed a comprehensive risk-based rule, known as the "Part 503" rule, to protect public health and the environment from the anticipated adverse effects of pollutants that may be present in sewage sludge that is applied to land. Using the results of the rule's multipathway risk assessment that considered soil background metal concentrations in the calculations of risk-based pollutant concentration limits, EPA set pollutant concentration limits above which sludge could not be applied. The limits were derived by calculating the increment of pollutant from sewage sludge that could be added to the total background receptor intake or plant uptake without exceeding a threshold dose. For human receptors, the threshold dose was set for noncarcinogens at the chronic effects RfD, and for carcinogens, at an incremental individual lifetime cancer risk of 10^{-4} . For non-human and plant receptors, background soil concentrations were subtracted from reference adverse effect concentrations to calculate the increment of a pollutant from sewage sludge that could be applied to soil without adverse impact. In short, soil-related background concentrations and risks were directly and quantitatively considered in this risk management decision.

The Office of Water has developed methods to set maximum contaminant level goals (MCLG) at concentrations at which no known or anticipated adverse health effects occur. Drinking water equivalent levels (DWEL) are calculated from RfDs by assuming a specific

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receptor body weight and consumption rate. The MCLG is set by multiplying the DWEL by the percentage of the total daily exposure expected to be contributed by drinking water (i.e., the "non-background" portion), called the relative source contribution (RSC). Generally, the Agency assumes that the RSC from drinking water is 20 percent of the total exposure, unless specific exposure data for a chemical is available, and that 80 percent of exposure comes from other sources. The RSC may be as high as 80 percent. The Agency also is using this approach of reserving a portion of risk to background in setting pollutant limits covered by the Food Quality Protection Act (FQPA) and in the Office of Pesticide Program's re-registration decisions.

EPA has not addressed in detail the issue of background risks or cumulative risks in RCRA hazardous waste listing determinations. In a recent hazardous waste listing determination for petroleum refining process wastes, analyses were conducted that considered multiple wastes disposed in land units (wastes with similar constituents from other sources) and multiple units at a facility, thus accounting for the impact of certain other background sources.

Difficulties in Addressing Background Risk

The Agency's lack of a generalized approach to considering background risk in its risk assessments and risk management decisions is demonstrated by the absence of discussion of background risks in many of its major rules and the simplified approaches used in rules that consider background concentrations. This may be due to mandates of environmental laws and the fact that accounting for all possible sources and routes of exposure to pollutants with similar toxic mechanisms is a complex and expensive task with many variables requiring much input data. Methods used to assess risk are evolving and new, more sophisticated models and strategies to assess multiple pathways of exposure are being developed. These models require many variables to accurately account for all sources of background risk, at least some of which are not likely to be available. Lack of data and funds required to collect the extensive data needed to assess multiple direct and indirect pathways has often resulted in the use of simplified assumptions and models such as limiting assessments to direct exposure pathways and regulatory decisions that set background contributions to conservative default values. What is considered background risk is also affected by the approach taken to define a "source" (e.g., whether the assessment of risk is performed on a source category basis or a point source basis).

Background concentrations are not static. The half-lives of contaminants are wide ranging and must be considered when assessing risks over a period of time. Persistent and bioaccumulating contaminants moving along the foodchain alter background concentrations over time. The exchange of contaminants between media (e.g., particulate deposition in surface water) also introduces a time-related background change. In addition, regulatory changes that reduce releases of contaminants from sources will, over time, alter background concentrations of those contaminants. For example, if drinking water standards (or other standards affecting exposure) are lowered for certain pollutants, exposures and any resultant risks from those pollutants are also lowered. Similarly, residual risk reductions in the incremental risk of some HAPs will ultimately reduce any associated background risk and consequently, overall risk of those pollutants. However, given the considerable uncertainties in risk assessment generally, it is

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not clear that a thorough consideration of background, even if possible, would greatly improve the overall conclusions of the assessment. An additional issue raised by the long residence time of certain HAPs is the relationship between the amount of emission reductions and the amount of risk reduction.

Defining Background for Residual Risk Analyses

Given the complexities associated with assessing cumulative risk from all chemicals and sources, background concentrations and risks for residual risk analyses will be assessed whenever possible on a chemical-by-chemical basis for the particular HAPs under evaluation. Although other chemicals may contribute to the cumulative background risk because of interactions or effects on the same target organ, the data needed to evaluate cumulative risks from multiple chemicals is quite extensive and difficult to collect. Thus, background concentration of a particular HAP for either an affected source or source category under evaluation is defined as the concentration of that particular HAP in environmental media attributable to natural and anthropogenic sources – both on-site and off-site – other than the source being evaluated. As described above, background concentrations may change over time, and analysis of background risks would be more accurate if these changes in background concentrations were accounted for. However, because of analytical complexity (e.g., data needs, modeling difficulty, high uncertainty), background concentrations generally will be based on a given point in time when taken into account for residual risk analyses.

Therefore, for the residual risk program, background concentrations will be considered from two perspectives: the contribution of HAPs from natural sources, and the contribution of HAPs from all anthropogenic sources other than the source under evaluation. For a particular point source at a facility, for example, the contaminants present in air in the absence of the source under evaluation may originate from natural sources as well as from other on-site and off-site emissions sources. It follows that the background risk is the cumulative risk from all possible natural and anthropogenic sources of a HAP other than the particular source or source category under evaluation. Residual risk may be assessed in the context of both kinds of background when the sources can be identified and their contributions measured and compared.

Strategy for Considering Background in Residual Risk Analyses

Residual risk analyses will assess incremental risk above background risk, and then assess the significance of these risk estimates using acceptable risk criteria developed and used historically for judging incremental risk. As described in this Report, residual risk will be addressed in a two-tiered approach. In the relatively simple screening tier of analysis, the residual risk analysis generally is performed without considering background at all. At most, local or regional scale estimates of background concentrations based on statistical analyses of monitoring data or screening-level modeling analyses (such as air concentration estimates developed in our cumulative exposure project) may be considered. This screening analysis is typically conducted using conservative methods and assumptions and results are compared to acceptable risk criteria. Where residual risk estimates exceed the criteria, a more refined analysis

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is conducted. In general, an in-depth modeling analysis of background concentrations will be beyond the scope of the refined analysis, although available background concentration data or other relevant information would be considered. As discussed above, a detailed analysis of background concentrations typically would require extensive data gathering and modeling beyond that required for the incremental risk analysis. For example, numerous nearby (and possibly distant) HAP sources of varying types would need to be characterized in sufficient detail to support release and exposure modeling. In some cases, background risks from HAPs potentially could be considered to play a critical role in evaluation of the need for further reduction of the incremental risk. Thus, for some source categories, or some individual sources, it may be determined that detailed analysis of background concentrations is warranted.

In such cases, the relative contribution of background to the total risk from HAPs would be considered in decisions for more stringent regulation and may influence the level of reductions required to obtain an "ample margin of safety." If the relative contribution of background risk is high compared to the incremental residual risk, additional source risk reduction may provide relatively negligible benefit. Alternatively, a high relative contribution to total risk by the incremental risk might strengthen the rationale for requiring more stringent regulation. As described above, EPA has reserved part of the "risk burden" for background risk in other regulatory programs (e.g., drinking water and pesticide programs), and this kind of approach will be considered in residual risk decision-making for HAPs. In the risk characterization step, EPA will consider and present the risk estimates in the context of the available information on background.

The data needs for assessment of background concentrations may differ depending on whether a source category or a specific source is under evaluation. For a specific source, identifying the background concentrations from other natural and anthropogenic emissions sources within a specified radius of the source will usually be considered sufficient to demonstrate the relative contribution of background to overall risk and the impact of the single source relative to other sources surrounding it.

4.2.3 Uncertainties in Risk Assessment Methods

This section responds to the CAA section 112(f)(1) requirement to address "any uncertainties in risk assessment methodology or other health assessment technique," with a focus on uncertainty in residual risk assessments. Uncertainty, when applied to the process of risk assessment, is defined as "a lack of knowledge about specific factors, parameters, or models" (EPA 1997c). When applied to the results of risk assessment, the term "uncertainty" refers to the lack of precision in the risk estimate due to uncertainties in the input assumptions, models,

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and parameter values. Examples of uncertainty relevant to the estimation of residual risks include a lack of knowledge about the nature of a dose-response relationship for a given HAP or a lack of data about pollutant emissions over time. Such uncertainties affect the precision and reliability of any risk estimates that were developed for individuals exposed to the substances (EPA 1988b). Even using the most accurate data with the most sophisticated models, uncertainty is inherent in risk assessment. Uncertainty is usually present in all stages of risk assessment. Although other taxonomies are sometimes used, sources of uncertainty in risk assessment are often described by the following categories (Finkel 1990):

- Uncertainty related to the conditions and circumstances of exposure (scenario uncertainty);
- Uncertainty in the structure of models used to estimate risks (model uncertainty);
- Uncertainty in the input values used in risk assessment models (parameter uncertainty); and
- Inherent heterogeneity (variability).

Uncertainty can be introduced into a health risk assessment at every step in the process. It occurs because risk assessment is a complex process, requiring integration of the:

- Fate and transport of pollutants in a variable environment by processes that are often poorly understood or too complex to quantify accurately;
- Potential for adverse health effects in humans as extrapolated from animal toxicity tests; and
- Probability of adverse effects in a human population that is highly variable genetically, in age, in activity level, and in life styles.

The presence of uncertainty in risk assessment does not necessarily imply that the results of the risk assessment are biased, only that the risks cannot be estimated beyond a certain degree of precision. One of the key purposes of uncertainty analysis is to estimate the degree of precision in risk estimates derived from uncertain scenarios, models, and parameters. In addition, uncertainty importance analysis can be used to identify the factors that contribute the most to the overall uncertainty in risk estimates. Efforts to refine scenarios and models or to gather more data can then be prioritized to provide the greatest reduction in risk uncertainty at the lowest cost.

Evaluating these different kinds of uncertainty in risk assessment may require different methods, as discussed in more detail later in this section. An important general property of uncertainty is that it can be reduced by gathering information. Where directly relevant data are not available, appropriately selected surrogate data may serve to reduce uncertainty.

The other important part of the general problem of “uncertainty analysis” is the need to characterize the potential *variability* of scenarios, models, and parameters and how such

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variability affects risk estimates. In contrast to uncertainty, variability has nothing to do with data quality or a lack of knowledge of fundamental relationships, but instead “refers to observed differences attributable to true heterogeneity” in the variables (EPA 1997c). Examples might include variations in hourly wind velocity or in the body weights among an exposed population. Because variability is an intrinsic property of the quantities being evaluated, it cannot be reduced by data gathering or refinements in models. Analyses of variability are still important, however, to assure that inputs to risk models are specified appropriately. For example, it may be found that certain HAP emission sources or exposed populations are heterogeneous, and more reliable estimates of risk can be developed by stratifying them and estimating risks separately for each group.

In the context of residual risks, uncertainty analysis has important implications both for risk assessment methods and for risk management. The following are among the key methodological issues that arise in the context of residual risk.

- Have all the important sources of uncertainty and variability in the scenarios, models, and input variables to the risk assessment been identified?
- What are the appropriate methods to evaluate uncertainty and variability, given the needs of the decision-making process, the capabilities of available models, and the data and resources that are available?
- What additional data or model refinements can be used to reduce uncertainty in the risk estimates?
- How can information about uncertainty be summarized and presented to decision-makers?

From the risk management perspective, important issues associated with uncertainty analysis may include the following:

- What are the most useful measures of uncertainty in risk estimates (from a risk management standpoint)?
 - What is a reasonable range over which the risk estimate might vary?
 - What is the level of certainty that the residual risk estimate is actually greater than zero or less than a defined LOC?
 - How reliably can the relative risks be compared? How well can risks be ranked?
 - What is the overall reliability of a specific risk estimate applied to a given decision?
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Clearly, risk assessment and risk management issues overlap. In the discussions that follow, the importance of adequate communication between the risk assessors and EPA risk managers is stressed.

Approaches to Addressing Uncertainty and Variability in the Estimation of Residual Risks

Systematic uncertainty and variability analyses have been used in support of risk assessment in a number of fields, most notably nuclear engineering, for over three decades. The use of uncertainty analysis in health risk assessment for exposure to chemical agents did not become widespread until the 1980s (Bogen and Spear 1987). Since then, a wide range of techniques for quantitative uncertainty analysis have been developed and applied to risk-related policy analysis (e.g., Morgan and Henrion 1990; Frey 1992; Hoffman and Hammonds 1994; McKone 1994; Hattis and Barlow 1996). In its 1994 report, *Science and Judgment in Risk Assessment*, NRC recommended that, when possible, uncertainty and variability should be quantified and the distinction between them maintained throughout risk assessment (NRC 1994). As discussed below, a number of techniques are available that allow the separate analysis of the impacts of uncertainty and variability on the overall dispersion in risk estimates.

The EPA has long recognized the need to consider uncertainty and variability in risk assessment. Agency guidance on these issues has gradually evolved over more than a decade, with major documents including:

- Initial set of risk assessment guidance documents (e.g., EPA 1986f,b);
- Risk Assessment Council (RAC) guidance (“the Habicht Memorandum,” EPA 1992e);
- *Guidelines for Exposure Assessment* (EPA 1992a);
- Policy and guidance for risk characterization (“the Browner Memorandum,” EPA 1995a,f);
- *Summary Report of the Workshop on Monte Carlo Analysis* (EPA 1996g); and
- *Policy for Use of Probabilistic Analysis in Risk Assessment* (EPA 1997k) and *Guiding Principles for Monte Carlo Analysis* (EPA 1997c).

Among these documents, the 1992 exposure assessment guidance, the 1997 *Policy for Use of Probabilistic Analysis in Risk Assessment*, and 1997 *Guiding Principles for Monte Carlo Analysis* provide the most detailed recommendations for uncertainty and variability analysis. The former document primarily provides technical guidance on uncertainty evaluation in the context of exposure assessment, while the latter two provide refined technical guidance, as well as recommendations on presentation of uncertainty information to decision-makers. The 1997 Policy also documents EPA’s judgment that probabilistic methods should be used wherever the circumstances justify these approaches. Thus, the Agency is committed to carefully considering use of quantitative methods for evaluating uncertainty and variability in its residual risk assessments. The Agency has also recently released a revised version of the *Exposure Factors*

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Handbook (EFH) that supports probabilistic approaches to the treatment of a number of commonly employed risk assessment input variables (EPA 1997g). In April 1998, the EPA Risk Assessment Forum convened a workshop on uncertainty analysis in which the problems associated with defining probability distributions for uncertainty and variability analyses were discussed.

As techniques for uncertainty analysis have matured, the Agency has come to endorse a tiered approach to such analyses. In residual risk and other air toxics analyses, EPA plans on addressing uncertainty in a tiered approach. In this way, EPA can efficiently utilize resources, mirroring the level of uncertainty analysis to the overall level of analysis. In the *Policy for the Use of Probabilistic Risk Analysis in Risk Assessment* (EPA 1997k), four general steps (tiers) in the recommended approach to quantitative uncertainty analysis are identified:

- Single-value estimates of high-end and mid-range risk;
- Qualitative evaluation of model and scenario sensitivity;
- Quantitative sensitivity analysis of high-end or mid-point estimates; and
- Fully quantitative characterization of uncertainty and uncertainty importance.

This approach starts with simple assessments of potential risks using both representative and more conservative scenarios, models, and input values, using point estimates of the major parameters. This approach may provide sufficient information for the policy question being addressed in some cases. For example, if risks for a suitably defined high-end receptor are far below levels of concern, then no additional uncertainty analysis (or risk analysis) may be needed to support a risk management decision. Such screening analyses will probably be appropriate as the first step in the analysis of residual risk uncertainty for all of the source categories.

Where the single-value high-end and mid-range estimates do not provide sufficient information about residual risk, additional analyses can be conducted to determine the likely range of uncertainty in these estimates, and the major factors that contribute to the uncertainty of the estimates. The sensitivity of the high-end and mid-point estimates to the specification of scenarios and models can usually be evaluated by conducting a manageable number of case studies using different model specifications and observing the resulting changes in risks. If scenario or model specification turns out to strongly affect risk estimates, a more refined analysis (see below) may be necessary.

In addition to the evaluation of scenario and model uncertainty, it may be desirable to evaluate the sensitivity of the point estimates of risks to variability and uncertainty in model input parameters. This may be done through sensitivity analysis or through the use of more detailed probabilistic methods. If sensitivity analyses are used, care must be taken to insure that the combinations of parameter values that have the greatest impact on risks are identified. For example, the greatest contributions to uncertainty may arise where two or more variables take

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values that are only moderately different from their mean values, rather than where either one of them takes an extreme value.

For some source categories, systematic sensitivity analyses would provide sufficient information regarding residual risks, and the uncertainties associated with these risks. If they do not, the next step is explicit probability modeling, most likely Monte Carlo or related simulation methods. Using such approaches, uncertainty and variability distributions can be defined for the major parameter values used in the derivation of the mid-range and high-end risk estimates. These distributions would then be used to develop Monte Carlo estimates of risk and risk uncertainty. There are many precedents for the application of such methods (Frey and Rhodes 1996) in the evaluation of potential risks from HAP sources.

Whether sensitivity analysis or simulation modeling is used, it is important to consider both uncertainty and variability at this stage of the analysis. Very often, key parameters in the residual risk assessment will be highly uncertain. Experience to date indicates that the emission-related parameters with a particularly high degree of uncertainty include measurements of emission rates, emissions inventories, ambient levels, and facility operating patterns that affect HAP releases. On the risk side, uncertainties in dose-response models, dose-response parameters, populations exposed, and behavior patterns associated with exposures seem to contribute significantly to the overall uncertainties in population risk estimates.

Where data are lacking or limited, it may be necessary to extrapolate beyond the range of available information, or use surrogate data where direct observations are not available, in order to develop estimates of parameter variability and uncertainty. The Agency is currently exploring a number of promising techniques in this area. Where relatively few data are available, statistical techniques such as bootstrap analysis may be used to develop variability and uncertainty distributions. Where important data are lacking, techniques for eliciting expert opinion (Morgan and Henrion 1990) may be useful in developing estimates of the uncertainty and variability of key parameters.

While these techniques can be very helpful in characterizing uncertainty, it is important that all assumptions and methods be fully documented, and that the available data sources be fully exploited before extrapolation or surrogate data are used. Decisions regarding the appropriate methods to be used in developing uncertainty distributions must be made on a case-by-case basis, carefully considering the specific needs of the analysis.

The final step in the analysis is a fully quantitative analysis of uncertainty and uncertainty importance. This approach is basically a more comprehensive extension of the previously described methods. In this case, however, rather than starting from pre-defined central-tendency and high-end risk estimates, all scenarios and models (to the extent possible) and all parameters are included in the modeling process as uncertainty and variability representations. Using standard two-dimensional Monte Carlo simulation methods, the effects of variability and

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uncertainty on the overall dispersion in risk estimates can be separated and quantified. In addition, the relative importance of individual sources of uncertainty can be evaluated through partial correlation coefficients, regression methods, contributions to variance, or related methods. However, the data requirements of such an analysis often limit its ability to be truly comprehensive.

Within the residual risk program, this option will be appropriate for sources or source categories where potential risks may indicate the need for a risk management action. The importance analysis could be used to guide data gathering to parameters where uncertainty is the greatest, or to define conditions (e.g., average emissions or operating conditions) for which risk estimates would not exceed levels of concern with a high degree of confidence.

Uncertainty and the Management of Residual Risks

It is important to recall that the underlying purpose of the evaluation of uncertainty is to improve the quality of the decisions that are made regarding the management of risks. In the context of residual risks, the primary purpose of the assessment is to support decisions about whether additional controls are needed, over and above initial MACT standards, to reduce risks to acceptable levels. Thus, at a minimum, the uncertainty analysis needs to supply risk managers with a defensible technical basis for decisions. The important questions to be addressed include: What is the risk? How reliable is the risk estimate? What is the expected reasonable range of outcomes if a specific decision is acted upon? To these might be added two other key "threshold" question, namely: Is there enough information to support a decision and, if not, what kinds of data are needed to reduce uncertainty to acceptable levels?

A well-conducted uncertainty analysis can provide defensible and well-qualified answers to all of these questions. If it is to do so, however, a substantial degree of interaction between risk assessors and risk managers is required. Preferably, this interaction begins early in the risk assessment process, when risk managers clearly articulate their information needs to the assessors, and assessors present options for meeting those needs. The interaction continues throughout the assessment process and into the risk communication phase, when the results of the analysis are formally presented to risk managers. The Agency has made efforts to explore the nature of the interaction that needs to occur and the nature of the informational needs of risk managers (Bloom 1993), and will continue to do so to assure that uncertainty analysis makes a constructive contribution to risk management decisions.

A second key purpose of the uncertainty analysis is to provide information useful to stakeholders involved in the decision process. As the federal government pursues its goals of expanded stakeholder involvement in risk management decisions (CRARM 1997a,b), a premium is being placed, as it should be, on providing information that is useful and intelligible to non-technical audiences. If support is to be secured for decisions, the decision rationale must be "transparent" and understandable to affected parties.

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The complexity of uncertainty evaluation, and particularly of probabilistic methods, may pose a significant barrier to understanding (and thus to the utility of the analysis). In the past, regulatory decisions have been evaluated primarily in terms of point estimates of risk and simple dichotomous decision rules. (If the point estimate of risk is above a certain level, take a certain action. If not, take another action.) In contrast, it may not be intuitively obvious, even to relatively sophisticated audiences, how to relate the outputs of quantitative uncertainty evaluation to a particular decision. For example, important aspects of the regulatory decision may rest on relatively subtle statistical distinctions (e.g., between a 95th percentile risk estimate and an upper 95th percentile confidence limit on a risk estimate), and the challenges in presenting such information can be formidable. In its recent guidance, the Agency has begun to define concrete approaches to the presentation of risk and uncertainty information to decision-makers and stakeholders. A promising approach involves relying heavily on narrative descriptions of uncertainty and simple diagrammatic presentations of risk information. These efforts will need to be continued and elaborated in the course of the Agency's residual risk assessments.

The question of how to present the results of uncertainty analyses overlaps with the more general problem of risk communication. As noted in Section 4.1.1, the Agency is required to report on the "public health significance" of residual risks. This level clearly has a probabilistic component; e.g., how certain does the Agency need to be that a risk is or is not "significant"? Is there some intermediate combination of risk and uncertainty that indicates the need for more data gathering, rather than immediate management? How can uncertain risks be compared and prioritized? The answers to these questions depend not only on the magnitude of the risks being evaluated and the magnitude of uncertainty associated with the risk estimate, but also on the specific control options available and their economic impacts. It will be important for the Agency to develop consistent approaches to defining the need for uncertainty evaluation for residual risk management and the larger air toxics program.

4.2.4 Negative Health or Environmental Consequences

This section addresses the CAA section 112(f)(1)(C) requirement to investigate and report on ". . . any negative health or environmental consequences to the community of efforts to reduce such [residual] risks." Pollution control technologies targeted at a single pollutant (e.g., a specific HAP) and single medium (e.g., air), especially conventional end-of-the-pipe treatment technologies, can inadvertently transfer pollutants and risks to different media, different locations, and different receptors, and can unintentionally create new and different risks in the process of controlling the targeted risk. Few control technologies, when viewed from a holistic, multimedia, life cycle perspective, are without health and environmental risks of their own. In the context of HAP residual risk, for example, a technology that removes a HAP from an air emission stream can produce contaminated water and/or solid waste, can require additional energy (which consumes resources and produces other pollutants), and in some cases may create new safety risks, especially for workers. Health or environmental consequences can be

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secondary to other consequences, such as the example of increased energy usage that may have environmental consequences.

EPA recognizes the possibility of creating or transferring risks as an unintended byproduct of actions that may be taken to reduce residual risks of HAPs. Thus, as part of the section 112(f) standard-setting process, the Agency will consider significant negative health and environmental consequences and the risk-risk tradeoffs associated with any future standards. One of the Agency's primary goals is to ensure that measures taken to reduce risk under section 112(f) authorities do not create other risk problems.

A key step in the residual risk process for HAP source categories determined to need additional risk reduction beyond the MACT standards in place will be the development and analysis of a range of risk management options. Ultimately, a risk management approach will be selected for the source category and a standard developed under section 112(f) to reduce risks to acceptable levels. As part of the analysis of risk management options – which will include evaluation of the effectiveness, reliability, emission and risk reduction, and cost of each option – EPA will consider the broad range of positive and negative impacts of each risk management option under consideration, rather than focusing simply on one criterion, such as control efficiency or cost. Information describing and, where practicable, quantifying potential negative consequences will be presented along with the other critical information to decision-makers responsible for selecting the risk management strategy. The Agency also plans to assess and consider, to the extent practicable, the uncertainty associated with its estimates of negative health and environmental effects, and also the uncertainty associated with its evaluation of effectiveness, reliability, and cost of risk management options.

In contrast to conventional air pollutant removal and treatment technologies, many pollution prevention approaches to reducing residual risks have fewer negative health and environmental consequences. This is primarily because pollution prevention approaches eliminate pollutants (and thus emissions) at the front end of a process rather than attempting to treat and dispose of them at some downstream step of the process. Thus, the Agency intends to identify pollution prevention approaches as risk management options and considers them in the standard-setting process. There will be a strong preference for selecting feasible and cost-effective pollution prevention approaches to reduce the residual risks of HAPs, in large part because they generally have fewer negative health and environmental consequences than other options.

4.3 Section 112 (f)(1)(D): Legislative Recommendations

Section 112(f)(1)(D) gives EPA the opportunity to make "recommendations as to legislation regarding such remaining risk" that may be identified during the analysis for residual risk.

The Agency is not proposing any legislative recommendations to Congress in this Report. At this time, EPA believes the legislative strategy embodied in the 1990 CAA Amendments

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provides the Agency with adequate authority to address residual risks and provides a complete strategy for dealing with a variety of risk problems. The strategy recognizes that not all problems are national problems or have a single solution. National emission standards will be promulgated to decrease the emissions of HAPs from stationary sources. The authority is also provided to look at smaller scale problems such as the urban environment or the deposition of HAPs to water bodies in order to address specific concerns, to focus or prioritize efforts to meet specific needs such as a concern for a class of toxic and persistent HAPs, and to allow for partnerships among EPA, States, and local programs in order to address problems specific to these regional and local environments. Congress developed a strategy that, when taken as a whole, provides EPA with the flexibility to identify and deal with a wide range of air toxics problems. As the EPA gathers data, performs risk assessments, and develops standards, EPA may reevaluate the adequacy of the CAA strategy.

Residual risk will play a major role as EPA moves into the risk-based phase of the CAA strategy. Using information gathered from a variety of sources, including Congressionally mandated studies, the residual risk program will provide part of the "safety net" that will insure that the public and the environment will be protected. The following chapter describes this program's strategy in more detail.

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5. The Residual Risk Analysis Framework

The remainder of section 112(f) – sections 112(f)(2) through (6) – describes the authority and schedule for setting residual risk standards. Section 112(f)(2) requires EPA to promulgate residual risk standards where necessary to provide an “ample margin of safety” to protect the public health and to prevent, taking into consideration costs, energy, safety, and other relevant factors, an “adverse environmental effect.” This chapter describes EPA's overall goals and framework for conducting residual risk analyses in response to sections 112(f)(2) through (6).

5.1 Legislative Context

5.1.1 The Context for the Analyses

Section 112(f) defines the context for residual risk standards to be the list of source categories or their subcategories that have been subjected to emission standards under section 112(d) of the CAA. On December 3, 1993, EPA established the promulgation schedule for technology-based (MACT) emission standards for 174 listed source categories (EPA 1993d). The source categories were divided into four groups, or bins, based on their expected promulgation date: 1992, 1994, 1997, and 2000 (also referred to as 2-year, 4-year, 7-year, and 10-year bins). MACT regulations are intended to identify and control air emissions from those major sources that emit HAPs listed pursuant to section 112(b) of the CAA. For existing sources in most source categories or subcategories, the minimum level of emissions reduction to be achieved is determined by establishing the current level of control of the best controlled 12 percent of the sources of emissions and establishing a “floor level” of emissions that is the average emissions limitation achieved by the sources in that 12 percent group. MACT emission reductions are based on source and technology analyses and do not consider risks presented by potential HAP exposures.

Congress intended risks to be considered eventually, however, as evidenced by the fact that most of the CAA-mandated air toxics programs other than MACT involve risk analyses and strategies to reduce risk to the public and environment. Congress stated in section 112(f)(2) that if a 112(d) standard does not reduce estimated lifetime excess cancer risk to the “individual most exposed” to less than one in a million, then the Administrator shall promulgate residual risk standards for the source category to protect the public health. EPA does not consider the one in a million individual additional cancer risk level as a “brightline” mandated level of protection for establishing residual risk standards, but rather as a trigger point to evaluate whether additional reductions are necessary to provide an ample margin of safety to protect public health. This interpretation is supported by the guidance provided in the September 14, 1989 *Federal Register* notice promulgating national emissions standards for benzene (i.e., the benzene NESHAP), which was cited by Congress in section 112(f) (see Section 2.1 for more discussion of the benzene NESHAP, and Appendix B for excerpts from the preamble to the final regulation). EPA

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plans to continue to use this guidance for making final risk management decisions under section 112(f) for carcinogens rather than adopting any single “brightline.”

Residual risk is one of the air toxics programs that begins to shift the emphasis from control technologies toward the receptors being exposed (i.e., the human populations or the particular environments). While the source category defines the range or scope of the data that will be required for performing residual risk analyses, the receptor defines the context for the characterization of the risk. The HAPs emitted, the routes of exposure, and the nature of the populations or environments being exposed become very important to the risk assessment outcome.

5.1.2 Compliance Schedule and Effective Date

According to section 112(f)(2), residual risk standards must be promulgated within eight years of the promulgation date of the MACT standard for that category unless the source category MACT was scheduled for promulgation within the first two years after the date of enactment of the 1990 CAA Amendments. In the latter case, residual risk standards must be promulgated within nine years. Therefore, for purposes of any residual risk standards, the eight-year limit applies to all source categories listed in the 4-, 7-, and 10-year bins, and the nine-year limit applies to categories listed in the 2-year bin, regardless of the actual promulgation date. This means that the 2-year bin standards promulgated under the residual risk program are due to be finalized in the year 2002 (earliest MACT promulgation for a category in the 2-year bin was 1993). Appendix C contains tables of the source category MACT standards, organized according to their promulgation schedule, and the actual promulgation dates of those that have been issued.

Section 112(f)(3) establishes that residual risk standards will become effective upon promulgation, although section 112(f)(4) provides existing sources subject to residual risk standards a 90-day time period after promulgation to comply, unless the Administrator grants a compliance waiver of up to two years. Actions must be taken during the waiver period to assure that “the health of persons will be protected from imminent endangerment.”

5.1.3 Area Sources (CAA Section 112(f)(5))

Area sources are defined as sources that have the potential to emit less than 10 tons/year of a single HAP or 25 tons/year of HAPs in aggregate. Section 112(f)(5) provides that the Administrator shall not be required to conduct a residual risk review of any category or subcategories of listed area sources for which an emission standard, referred to as Generally Available Control Technology (GACT), is promulgated under section 112(d)(5). The EPA interprets this statutory language to mean that any area source for which the emission standard is based on MACT will be included in the residual risk analyses according to its specific schedule of promulgation, but an area source for which GACT was the basis of the standard will be reviewed under the residual risk program only if deemed necessary by EPA. Area sources to which MACT has been applied are identified in Appendix C.

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In an effort to utilize our resources wisely and maximize the information gained from the residual risk analysis process, source category analyses may include area sources not subject to MACT or GACT. The results of those analyses, with regard to such area sources, would then be considered under the relevant components of our overall air toxics program, such as the Urban Air Toxics Strategy.

5.1.4 Unique Chemical Substances (CAA Section 112(f)(6))

There are 17 HAPs listed under section 112(b) that are not specific individual compounds and for which no CAS numbers are given (see **Exhibit 19**). Eleven of these are classes of metal compound HAPs, and the rest cover a variety of other HAP classes. Congress has directed in section 112(f)(6) that in setting residual risk standards applicable to sources that emit any of these HAPs, the Administrator should consider information on the HAP that is actually emitted. Each of these HAP classes may contain hundreds of individual compounds for which there may be very limited or no toxicity, emissions, or other risk-related data.

In the screening tier of analysis, we may default to relying on data from unspciated HAPs in this category of “non-CAS number HAPs” as the basis for evaluating risks, or use data for one member of a class as a surrogate for other members of the class that have data gaps. In the absence of toxicity, emissions, and other risk-related information about the specific “non-CAS number HAPs” that may be emitted by a source under study, we will continue to use information that is available on any of the constituents, including the elemental compounds, as scientifically appropriate. Where substance-specific data are available, we will use those data. In analyses that may form the basis for risk reduction/risk management decisions, assumptions about a group or members of a group will be carefully evaluated for scientific appropriateness.

An additional requirement of section 112(f)(6) is that any direct transformation byproducts resulting from the emissions of any of these classes of HAPs should be the basis for setting standards.

5.2 Objectives

The objectives for residual risk activities under section 112(f)(2) are two-fold.

- (1) Assess any risks remaining after MACT standard compliance; and
- (2) Set standards for the identified source categories, if additional HAP emission reductions are necessary to provide an ample margin of safety to protect public health or, taking into account cost, energy, safety, and other relevant factors, to prevent an adverse environmental effect.

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EXHIBIT 19
17 HAP CLASSES LISTED UNDER CAA SECTION 112(b)

Antimony Compounds	Lead Compounds
Arsenic Compounds (inorganic including arsine)	Manganese Compounds
Beryllium Compounds	Mercury Compounds
Cadmium Compounds	Fine Mineral Fibers ^c
Chromium Compounds	Nickel Compounds
Cobalt Compounds	Polycyclic Organic Matter ^d
Coke Oven Emissions	Radionuclides (including radon) ^e
Cyanide Compounds ^a	Selenium Compounds
Glycol Ethers ^b	

- ^a X'CN where X = H' or any other group where a formal dissociation may occur. For example, KCN or Ca(CN)₂.
- ^b Includes mono- and di-ethers of ethylene glycol, diethylene glycol, and triethylene glycol R-(OCH₂CH₂)_n-OR' where:
n = 1, 2, or 3
R = alkyl or aryl groups
R' = R, H, or groups which, when removed, yield glycol ethers with the structure:
R-(OCH₂CH₂)_n-OH.
Polymers are excluded from the glycol category.
- ^c Includes mineral fiber emissions from facilities manufacturing or processing glass, rock, or slag fibers (or other mineral derived fibers) of average diameter 1 micrometer or less.
- ^d Includes organic compounds with more than one benzene ring, and which have a boiling point greater than or equal to 100°C.
- ^e A type of atom which spontaneously undergoes radioactive decay.

We will evaluate source categories for which MACT standards are promulgated under section 112(d) using the direction provided in section 112(f) and the risk assessment methods described in Chapter 3. The general framework for the risk analysis process is described in Section 5.3.

The MACT program is achieving substantial emissions reductions across many HAPs and industries. In doing so, it is reducing risks and also leveling the emissions playing field within industry types. The residual risk framework is intended to provide the Agency flexibility in its decisions while ensuring that public health and the environment are protected. Our objectives also include continuing the partnership with State and local programs in the sharing of data and expertise, and including groups who may be affected by residual risk decisions as part of the process, when it appears feasible and appropriate to do so.

5.3 Residual Risk Assessment Strategy Design

Using the context provided by Congress in section 112(f) and the methodologies, data, and assessment process for air toxics described in more detail in previous sections of this Report, EPA has developed a residual risk framework. The framework for residual risk analysis may be described in several steps: identifying management goals that reflect the legal requirements, problem formulation, data collection, exposure and toxicity assessment, risk characterization, and risk management/risk reduction. **Exhibit 20** presents a flowchart of the general residual risk analysis process. In short, the framework calls for an iterative, tiered assessment of the risks to humans and ecological receptors through both direct and multipathway exposures to HAPs, leading ultimately to a decision on whether additional emission reductions are needed for individual source categories. This type of iterative or tiered approach is consistent with the NRC (NRC 1994) and Risk Commission (CRARM 1997a,b) reports written pursuant to the 1990 CAA Amendments.

The first component of the residual risk framework is that EPA state its risk management goals, which are identified at a broad level in the CAA legislation:

- to achieve a level of emissions that ensures that the public health is protected with an ample margin of safety; and
- to ensure, taking into account cost, energy, safety, and other relevant factors, that the above level of emissions do not result in an adverse environmental effect.

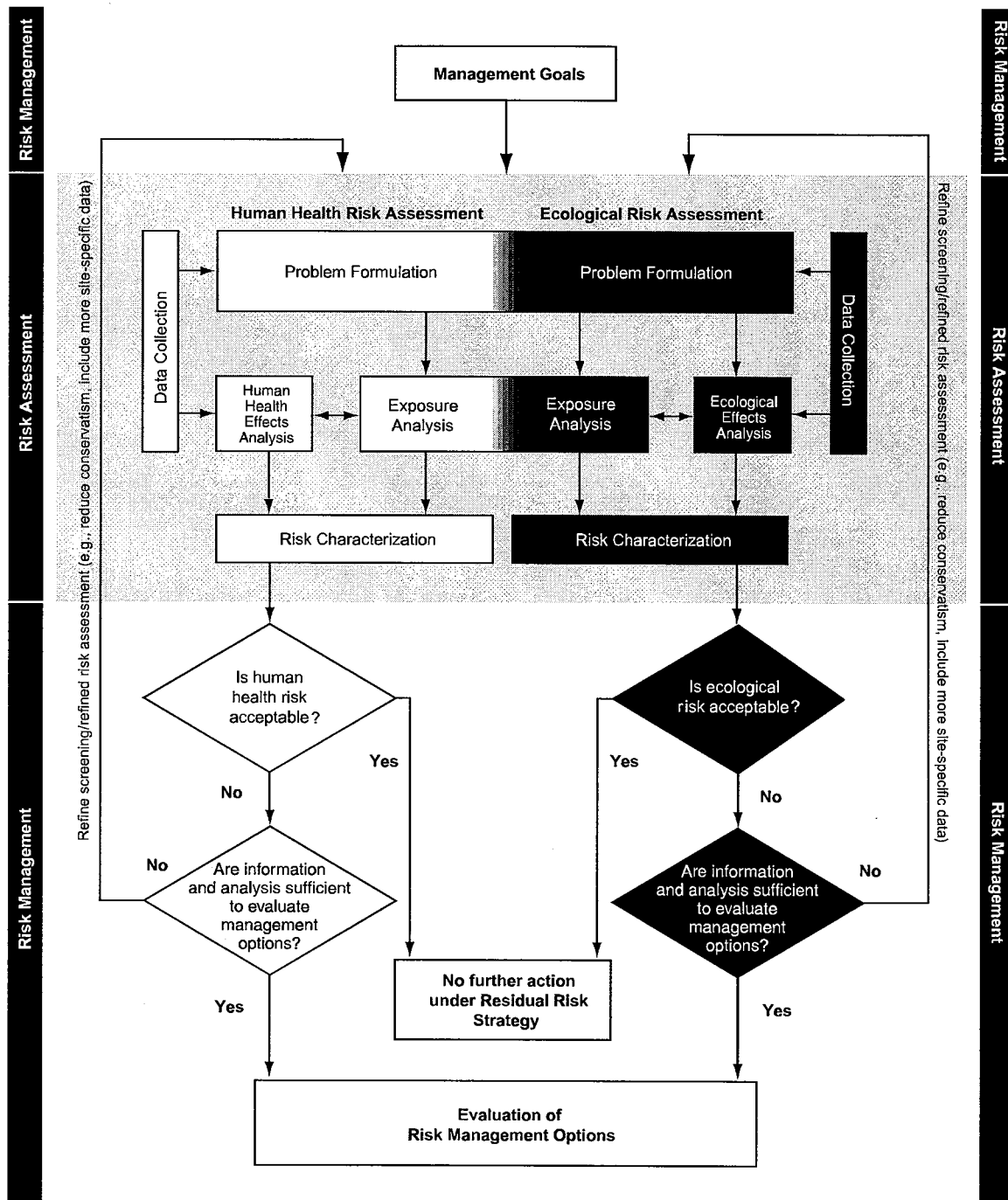
EPA may decide to translate those legislative objectives into more specific management goals. Those management goals help direct the problem formulation phase of both the human health and ecological risk assessments.

For both the human health and ecological risk assessments, the basic premise of the tiered approach is that the early analysis is generally screening in nature. This analysis is designed to be relatively simple, inexpensive, and quick, use existing data and defined decision criteria, and rely on models with simplifying, conservative assumptions as inputs. These simple default assumptions are conservative in nature to ensure that a lack of data does not result in overlooking a source category that may pose significant risk. A more refined analysis requires more resources and data, but the results are more certain and less likely to overestimate risk. While the strategy is represented generally as having two tiers (screening and refined), additional analyses might be performed within one or both tiers. The key point is that the additional analyses of increasing complexity (and resource requirements) will be performed in a manner EPA determines is cost-effective for a given source category. Where the available information indicates the potential for substantial risks, a more refined analysis might be implemented at the start.

In using this approach, EPA will follow the recommendation of the NRC (1994) which stated "EPA should use bounding estimates for screening assessments to determine whether

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EXHIBIT 20
OVERVIEW OF RESIDUAL RISK FRAMEWORK
ITERATIVE APPROACH



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further levels of analysis are necessary. For further analysis, the committee supports EPA's development of distributions of exposures based on actual measurements, results from modeling, or both." The EPA believes that the analysis being evaluated for use in screening-level assessments does, in most cases, produce bounding estimates. However, if this iteration is so conservative that source categories will not be screened out for further consideration under the residual risk program, an additional iteration that uses less conservative assumptions will be evaluated and used. In the refined analysis, the exposure assessment will provide distributions of exposures and a probabilistic distribution of risk will be estimated.

As shown in Exhibit 20, the human health and ecological risk assessments for a source category are organized into three phases: (1) the problem formulation phase, in which the context and scope of the assessments are specified; (2) the analysis phase, in which the HAPs' toxicity and exposure to humans or ecological receptors are evaluated; and (3) the risk characterization phase, in which the toxicity and exposure analyses are integrated to assess the nature, magnitude, and uncertainty of any risks. Also as illustrated in Exhibit 20, the problem formulation and analysis phases of the human health and ecological risk assessments will partially "overlap" in that certain pathways of concern for humans (e.g., inhalation of outdoor air, consumption of contaminated fish) will in some cases also be pathways of concern for some ecological receptors (e.g., terrestrial wildlife, fish-eating wildlife). The development and conduct of risk assessments by this three-phased approach are described more fully in the Agency's ecological risk assessment framework (EPA 1992b) and guidelines (EPA 1998d). Although described in those documents in the context of ecological risk assessment, the basic phased approach is also appropriate for human health risk assessment.

Following the risk characterization phase of each assessment, a decision step occurs. How much the risk estimates can be improved by refining the analysis is an important consideration at this step. If no unacceptable risks have been identified for human health or environmental effects and the analyses are adequate to support those conclusions (i.e., risks are acceptable), then no further action is required under this process, and the results of the risk assessment should be documented. If human health or environmental risks appear unacceptable, and if sufficient information is available to evaluate management options considering risks, costs, economic impacts, feasibility, energy, safety, and other relevant factors, the risk assessment is complete (i.e., no additional iterations are needed), and the process moves to risk management decision-making. If the information from the risk characterization is insufficient to fully evaluate risk management options, the residual risk assessment should proceed to a still more refined analysis.

5.3.1 Stakeholder Involvement

As the federal government pursues its goals of expanded stakeholder involvement in risk management decisions, consistent with recent recommendations of the Risk Commission (CRARM 1997a,b) and the NRC (NRC 1996), EPA is committed to involving stakeholders, as appropriate, at various stages throughout the residual risk analysis process. The NRC's

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Understanding Risk presents a risk assessment/risk management model that also emphasizes extensive interaction and involvement of stakeholders. Thus, an important component of this process will be the establishment of interactive discussions with the parties involved. In the residual risk analysis process, EPA expects the level of stakeholder involvement to vary for the different source categories, depending on the complexity of the analysis and the potential risks involved. For source categories with the potential for higher risks and more complex analyses, stakeholder involvement is likely to occur more frequently throughout the process.

The stakeholders in this case are State and local public health and air toxics agencies, Tribal groups, the affected industries, and public interest groups. The purpose of these interactions may be to identify available data, to discuss the results of the risk assessments, to determine the nature and the scope of the potential risks, to hear concerns and perceptions about the level of risk, to discuss the next steps in the process (e.g., need for refinements to the analysis), and to discuss the options available to reduce risk if necessary. Stakeholder involvement adds another dimension by allowing affected parties to have input and to be given the opportunity to understand the views of other participants. Feedback from stakeholders, including those whose concerns may extend beyond the technical capabilities of modeling to better discern the complete problem, may assist in our evaluation of results. For example, while the scope of the residual risk analyses will be national, it is possible that local, State, or regional level problems would only be brought to light by groups at that level. As noted above, stakeholder involvement may not be the same for all analyses. The level of stakeholder involvement may be driven by the complexity of the analyses and the expected impacts of decisions that will result from the analyses. With regard to ecological risk assessments, stakeholder input can also be valuable in characterizing the societal importance of the ecosystems at risk.

At important points in the process, the Agency will make information available to State and local public health and air toxics agencies, Tribal groups, affected industries, and concerned public interest groups, and may take other steps to facilitate meaningful stakeholder participation. Those with concerns, specific interests, or information about the specific source category are encouraged to provide input and assist in the process by pointing out source categories or HAPs of concern, or by identifying issues to consider. In addition, the Agency expects that stakeholders will bring valuable new data on HAP toxicity, emissions, or exposure to its attention. In the problem formulation phase and more extensive data collection step of refined risk assessments, involvement of stakeholders, specifically affected industries and State and local agencies, is especially important. As the process for a source category moves closer to risk reduction/risk management decisions, stakeholder involvement is considered more critical. The opening of a stakeholder dialogue, consistent with legal limitations such as the Federal Advisory Committee Act, provides the opportunity for all groups to be involved early in the risk management process and for the implementation of a rational risk reduction strategy that proceeds from mutual understanding rather than a one-sided argument.

5.3.2 Priority Setting

Priority setting among the large number of source categories to be reviewed – that is, determining the order in which residual risk assessments for specific source categories will be conducted – also is a critical part of the overall strategy. EPA intends to set priorities based on a number of considerations, including the actual MACT promulgation dates for source categories (which determines the statutory time period for residual risk determinations) and any available information bearing on the level of residual risks attributable to various source categories. While meeting statutory deadlines, EPA will, to the extent possible and based on the available data, set priorities aimed at achieving the largest, most cost-effective risk reductions first. Priority setting also will be iterative; priorities are likely to be revised during the course of the residual risk program as new information becomes available and initial analyses are performed on various source categories.

Prioritization may occur at many stages of the process. For example, information collected in the initial problem formulation step will help in setting priorities for a screening-level analysis. Results of the screening analyses will aid in determining the need for and setting priorities for a refined analysis. It is also noted that results of screening and refined analyses are expected to contribute to our priority setting with regard to new research, data collection, and tool development.

As discussed in Section 5.1.2, the MACT promulgation dates, which determine the statutory time period for residual risk determinations, fall into four “bins” (2-year, 4-year, 7-year, and 10-year). Section 112(f)(2) requires standard-setting to address residual risks within eight or nine years of the promulgation of MACT standards. As a practical matter, this establishes a tight timeframe in which to develop the information necessary for conducting and refining screening analyses and in using this information for priority setting. The later two bins, the 7-year and 10-year, contain many more source categories than the earlier ones. Given the greater number of source categories in these later bins, priority may be largely driven by the residual risk statutory deadlines. The Agency’s intention is to consider other factors as described above. The extent to which this is feasible may vary for the later bins and will be determined as we initiate the process for those source categories.

5.3.3 Problem Formulation and Data Collection

Residual risk analysis for a given source category will begin by describing the context and scope of the problem to be evaluated. As much data as are readily available will be used at this stage of the assessment, and stakeholders with interest in this category may be encouraged to provide input. Information from State, local, or Tribal entities may help the planning process by pointing out source categories or HAPs of concern, or by identifying issues to consider. It would be at this stage that key decisions about the HAPs of concern would be made and reassessed in any subsequent iteration of analysis. For example, do the HAPs being emitted trigger the need for human health or ecological assessments of pathways other than inhalation? What are the

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endpoints of concern, and what populations may be most affected by the HAPs being emitted? These evaluations may be largely at a qualitative level, but they will inform the design of the analysis to follow, in either a screening or refined level.

As discussed in the previous section, the timing of the MACT promulgation schedule, as well as the need for efficient utilization of resources, will require some prioritization of work. A number of source categories may be scheduled for analyses during the same time period. The problem formulation phase will help to prioritize which source categories need earlier attention. It also will help to determine what data are needed to support certain decisions and whether those data are available.

Designing the risk assessments during problem formulation involves the following main activities:

- Characterize key sources of HAP release;
- Characterize environmental behavior of HAPs and determine for which, if any, multipathway analyses might be required;
- Identify need for ecological assessment;
- Identify receptors that are potentially at risk;
- Select assessment endpoints; and
- Identify exposure pathways of concern.

Many types of data from a wide variety of data sources are needed to assess the residual risks of source categories. Data collection is expected to occur throughout the residual risk assessment process. Some data collection is needed even before any screening analyses are begun on individual source categories, to serve as a basis for setting priorities and ordering the source categories for residual risk assessment. Because the screening assessment is intended to be based on readily available data, data collection for this step generally will involve gathering and organizing the existing data (e.g., health and environmental effects of HAPs, post-MACT source emission rates for HAPs, previously performed risk assessments of source emissions), generally from EPA sources (e.g., MACT rulemaking docket, MACT data base) and State and local air toxics agencies.

The data available will, in part, determine whether an analysis is done on specific facilities in a source category or on model plants of the type developed during MACT rule development. EPA anticipates that the amount of information available about facilities within a source category may be more extensive after the Agency promulgates a MACT standard versus what was known during MACT rule development. Some of the additional information anticipated is increased knowledge of the HAPs being emitted, the regulatory level or estimated emission reductions for these HAPs, the locations of the facilities subject to a MACT rule, and whether a specific facility is in compliance with the rule. This type of information could narrow the scope of the analysis to those facilities that appear most likely to be a residual risk concern.

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Problem formulation, including establishment of the conceptual model, sets the context and scope of human health and ecological risk assessments. For the initial assessment, it also includes an evaluation of the potential for specific HAPs to accumulate in the environment, which influences the need for multimedia analyses.

Information on the potential for HAPs to accumulate in the environment can be used to narrow a comprehensive set of assessment endpoints in the ecological risk screen. Given that HAPs are initially released to the air, the most important question for the initial problem formulation is the degree to which the HAPs might persist and partition into other environmental media. If a HAP is unlikely to accumulate in the environment, then only those ecological communities that come into direct contact with HAPs in the air need be considered. The question of whether a multipathway analysis is needed is also asked during problem formulation in the human health risk assessment.

To identify HAPs that are likely to accumulate in the environment, and thus potentially pose risks (ecological and/or human health) via food chains and other environmental media, the most important HAP characteristics are environmental persistence and bioaccumulation potential.

***environmental
persistence***

If field data, chemical property data, or inference from chemical structure suggest that the HAP will persist in the environment for several weeks to several years (or longer), then a multimedia analysis might be necessary. For persistent and non-volatile HAPs, it is likely that the HAP will be deposited and accumulate over time in aquatic and terrestrial systems downwind of the source.

bioaccumulation

If field data, laboratory data, models (e.g., food web), and/or the log K_{ow} suggest that the HAP might accumulate in plant or animal tissues, then a food chain analysis might also be needed. Various cutoff values for screening bioaccumulation potential have been used. For example, the *Final Water Quality Guidance for the Great Lakes System* (EPA 1995e) used a bioaccumulation factor (BAF) in fish of 1,000 to identify bioaccumulative chemicals, and log K_{ow} values from 3.0 to 5.0 have been used to identify constituents likely to bioaccumulate in aquatic and terrestrial ecosystems (e.g., Connell 1988; Garten and Trabalka 1983; Suter 1993).

Where possible in the screening assessment, environmental characteristics that influence the behavior of a HAP in different media (e.g., persistence in water versus air) and thus their potential exposure to different ecosystems will be identified. For example, if a HAP is readily degraded by hydrolysis in surface water, aquatic life might not be at risk even if the HAP is toxic and persistent in air and deposits to surface waters, into which it readily partitions. In a refined

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ecological risk assessment, a literature search and review of studies that describe ecological impacts that have been clearly attributed to the HAP, or field measurement studies that indicate environmental “sinks” for the pollutant (i.e., in what environmental compartment(s) the pollutant is likely to accumulate), can be useful.

For ecological risk assessment, the screening step may also include selection of HAPs for analysis based on their relative toxicity. For some source categories, several HAPs might be released. It is possible that the environmental behavior of several HAPs is such that they are expected to partition into the same environmental medium. If information is available to indicate that one or a few of those HAPs are much more toxic to ecological communities in contact with that medium than the remaining HAPs, then it might be possible to focus the ecological screening assessment on the most toxic of those HAPs. If, in the screening analysis, the most toxic of those HAPs indicate no risks, then the less toxic HAPs may not need to be evaluated further.

Developing the Conceptual Model

The conceptual model for a residual risk assessment includes a description of the sources of HAP releases, information on emission rates, and a description of exposure pathways, assessment endpoints, and the measures that will be used to evaluate the assessment endpoints. Multimedia analyses are likely to be needed for many of the persistent HAPs, whereas only the air pathway may need to be considered for some short-lived HAPs. For those HAPs that are not expected to accumulate in the environment, either locally or regionally, the conceptual model is relatively simple, and can be assumed to involve inhalation of air by humans and terrestrial animals and direct exposure of plant foliage to the air. For those HAPs that might accumulate in other environmental media (e.g., in water, sediments, soil, or plants), a multimedia exposure model with the appropriate receptor communities will be needed.

In ecological risk assessments, the various environmental communities need to be carefully considered. For HAPs that are likely to partition into sediments and soils, receptors of concern include the benthic aquatic community, the soil macro- and microinvertebrate community, and plants. For HAPs that are likely to partition into water, the benthic and free-swimming aquatic communities should be included. For HAPs that might bioconcentrate or bioaccumulate in aquatic organisms, the animals that feed on those organisms should be considered (e.g., piscivorous wildlife). For HAPs that might bioaccumulate in terrestrial plants, herbivorous animals should be included in the conceptual model.

5.3.4 Screening Analyses

Screening-level analyses will often be applied as a first step in the assessment of both human health and ecological risks, and may include other pathways in addition to inhalation as appropriate (see discussion in Section 5.3.3). When a screening assessment is complete, EPA will assemble the information it has collected, as well as the results of the screening analysis, to

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prepare a characterization of the source category that would describe any potential public health or environmental concerns. This information may include both quantitative and qualitative data and results; at this level, any quantitative exposure and risk estimates will generally be point estimates (not probabilistic estimates). The screening assessment results will typically be used to eliminate low-risk source categories from further consideration, to prioritize the remaining source categories as to the need for a refined assessment, and also to focus any refined assessment so that it is done more efficiently.

While the screening analysis can serve as a basis for a decision to pursue additional analyses or to eliminate low-risk source categories from further consideration under section 112(f), it may not be adequate to serve as a basis for establishing additional emission reduction requirements under section 112(f). These analyses are typically conservative in nature and specifically designed to more likely overestimate than underestimate risks (yielding a certain level of false positives). Their results should not be misinterpreted to provide a realistic prediction of risk. That is, the purpose of a screening analysis is to identify those situations or HAPs for which no further action is needed and those for which further analysis is needed. When a subsequent analysis is performed, those aspects of the analysis that are thought to influence risk most or contain the greatest uncertainty are refined.

The screening analysis will rely largely on readily available data, use simple approaches to estimate emissions, use simple fate and transport models, use simple multimedia models (with simple conservative bioaccumulation factors and models of transfer of HAPs from air and soils to plants, or from air and water to biota), and incorporate readily available toxicity values. The approximate physical locations of the HAP emission sources are determined from available information such as emissions profiles derived from the development of MACT source categories, the Background Information Documents for proposed MACT standards, and MACT model plants data.

Human Health

Screening analyses will rely largely on readily available data and incorporate readily available toxicity values. The general methods to be followed are described in Chapter 3.

Depending on the expected magnitude of risk and ready availability of appropriate data, the maximum off-site modeled concentration may be used to estimate the most exposed individual in screening-level risk assessments. Where risks are expected to be elevated, in order to conserve resources, we may pass over this conservative assumption step and move to a refined assessment that incorporates population data in order to derive the MIR (maximum individual risk) for areas that people are believed to occupy. Because screening-level risk assessments will be used for the purpose of determining whether or not further analysis and concern are warranted, the MEI estimate may be used for risk management decisions that result in the judgment not to regulate a given source category, but will not be used for risk management decisions that call for additional controls or regulatory actions.

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When a screening assessment has been conducted for a source category, the risk characterization will typically be used by EPA managers to decide if a more refined risk assessment should be conducted or if nothing more needs to be done under the residual risk program. As described in Section 5.3.1, stakeholder involvement at this point may be valuable.

Criteria for Evaluating Screening Analysis Results. Exhibit 21 summarizes human health risk assessment assumptions and criteria for the screening level of analysis and for the more refined analysis. EPA will consider a wide range of available toxicity values in determining if the continued emission of HAPs poses a risk to the public or the environment. When EPA-verified toxicity values are not available, other sources of toxicity values may be used (see Section 3.4.1).

Cancer. In the assessment of cancer risks, dose-response assessments developed in a manner consistent with the direction of the 1996 proposed cancer guidelines (EPA 1996b), which utilize information on the mechanism of action more than the previous guidelines (EPA 1986b), are preferred. For early screening analyses, a linear mechanism will be assumed (unless an EPA assessment is complete which assumes otherwise). Screening analyses may assume additivity of individual HAP associated cancer risks. Where the screening risk results are below a 10^{-6} level of risk, excess cancer risks will usually be considered acceptable and no further action will be necessary under this process.

Non-cancer effects. Acute and chronic exposures will be assessed separately. For chronic exposures, long-term exposure estimates (e.g., annual average) will be used. For acute risks, a similar analysis will occur except that short-term exposure estimates (e.g., one-hour averages) will be used. In early iterations of the screening analysis, the health criterion for all non-cancer assessments (acute and chronic) may be based on the hazard index (HI) calculated by assuming additivity of HAPs in a mixture, where plausible. For each HAP emitted from a source category's facilities, the toxicity value will be compared with the upper-end HAP exposure level, as determined in the exposure screen, resulting in a hazard quotient (upper-end HAP exposure level \div toxicity value (such as the RfC)). In a screening analysis, the hazard quotients for each HAP in the mixture may be added regardless of endpoints, resulting in an HI value. This will result in a more conservative outcome than looking at HAPs individually, or than looking at different endpoints separately. In a more refined analysis, the assumption of additivity may be reviewed and limited to HAPs for which the assumption has a plausible basis or for which no data are available to support its rejection. A more refined risk assessment will likely be conducted when the HI exceeds 1 in the screening analysis (i.e., when exposure estimates exceed toxicity reference levels).

Ecological

Not all HAPs will automatically be considered in ecological risk analyses. Consistent with EPA guidelines (EPA 1998d), priority will be given to certain HAPs based on their environmental behavior and toxicity. As discussed in section 5.3.3, HAPs with the potential for

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EXHIBIT 21
SUMMARY OF ASSUMPTIONS AND CRITERIA FOR EVALUATING PUBLIC HEALTH RISKS

Component of the Risk Assessment	Screening Level^a	Refined^b
Problem Formulation	<ul style="list-style-type: none"> ▶ From readily available information, identify HAPs for analysis ▶ Identify HAPs that require multipathway analysis ▶ Use generic multimedia conceptual model simplified based on HAP characteristics and likely exposure pathways, 	<ul style="list-style-type: none"> ▶ Screening analysis results or other information used to identify HAPs and exposure scenarios for assessment ▶ Screening analysis results or other information used to identify multipathway HAPs of concern ▶ More site-specific multimedia model
Analysis Phase	<ul style="list-style-type: none"> ▶ Simple conservative assumptions and screening-level exposure models are used ▶ In early iterations, assume additivity for all HAPs; refine this assumption as scientifically appropriate in later iterations ▶ Variety of sources relied upon for toxicity values ▶ Conservative individual exposure estimate (may use theoretical MEI in early iterations) ▶ Size and nature of potentially exposed population not necessarily considered ▶ Simple analysis of uncertainty 	<ul style="list-style-type: none"> ▶ Where scientifically appropriate, assume additivity for HAPs ▶ More careful consideration of toxicity value basis and source ▶ Evaluate population distributions of exposure and risk ▶ More refined uncertainty analyses
Criteria	<ul style="list-style-type: none"> ▶ Upper-end individual cancer risk $<10^{-6}$ generally considered acceptable ▶ Upper-end individual cancer risk $\geq 10^{-6}$ may lead to refined analysis ▶ HI < 1 generally considered acceptable ▶ HI ≥ 1 leads to reexamination of additivity assumptions and if HI still greater than 1, may lead to refined analysis 	<ul style="list-style-type: none"> ▶ Upper-end individual cancer risk $<10^{-6}$ generally considered acceptable ▶ Upper-end individual cancer risk of roughly 1 in 10,000 is ordinarily considered the upper end of the range of acceptability ▶ Decisions on unacceptable risk will be made on a case specific basis, considering information including confidence in the risk estimate, population size, distribution of risk within the population, presence of sensitive subpopulations at various risk levels, the effects of concern, uncertainties in the effects information, and other factors

^aScreening assessment may be based on upper-end estimated HAP exposure at the location of either the hypothetical MEI or the MIR in locations people are believed to occupy. Available toxicity values will be considered.

^bRefined assessment based on more detailed and site-specific, and less conservative, estimated HAP exposures at the MIR location and throughout the spatial area of impact. EPA consensus toxicity values, or equivalent, reviewed in light of any additional credible and relevant information, are typically used.

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adverse environmental effects due to a particular ability to persist, bioaccumulate, or exhibit acute toxicity will be considered high priority in analyses for environmental risks. It is likely that this will result in the identification of only a small minority of HAPs that will entail quantitative risk analyses.

For both screening and refined assessments, the analysis phase of the ecological risk assessment involves two main steps: estimating HAP concentrations in the environment (including biota, where appropriate) and evaluating exposure-response profiles. In the initial screening assessment, point estimates for both the HAP concentrations in the environment and for ecological effects will generally be used.

A main purpose of the screening-level ecological risk assessment is to screen out those HAPs and sources of HAPs that are unlikely to pose threats to ecological receptors based on readily available information. Because information on the habitats and ecosystems surrounding individual facilities of a source category generally is not readily available, for purposes of the screen, EPA generally assumes the presence of generic ecological systems and receptors. The simple multipathway analysis is employed to estimate if, and to what extent, generic ecological receptors may be exposed to HAPs. Using the approximate source locations, a generic ecosystem model including representative environmental and ecological receptors for the sites at risk is developed. The exposure and potential impact are then modeled and predicted concentrations in the various environmental media are compared to available ecotoxicity criteria (i.e., point estimates of thresholds for ecological effects). Ecotoxicity criteria are described in Section 3.4.2.

EPA assumes, for purposes of screening, that if the most sensitive species known to occur within an ecological community is protected from adverse effects caused by a HAP, the structure, and therefore the function, of the community also will be protected. Protection of the ecosystem as a whole is inferred from the protection of its component communities. These assumptions are consistent with those made by the Office of Water in developing ambient water quality criteria for the protection of aquatic life and with those made by the Office of Solid Waste in developing a variety of screening ecotoxicity criteria. These assumptions will need to be carefully evaluated as the ecological risk assessment methodology for residual risk is developed.

Criteria for Evaluating Screening Analysis Results. The results of the screening exposure and ecological effects assessments are integrated to characterize risk. In the screening-level ecological risk characterization, the maximum HAP concentrations estimated for the various environmental media are compared to the appropriate screening-level ecotoxicity criteria for each ecological community specified in the conceptual model. The ratio of the estimated environmental concentration to the ecotoxicity criteria is called the hazard quotient. When the hazard quotient exceeds 1, a more refined assessment may be needed. **Exhibit 22** summarizes the assumptions and criteria used to evaluate environmental risks for the screening analysis and for the more refined analyses.

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EXHIBIT 22
SUMMARY OF ASSUMPTIONS AND CRITERIA FOR EVALUATING ENVIRONMENTAL RISKS

Component of the Risk Assessment	Screening Level	Refined^a
Problem Formulation	<ul style="list-style-type: none"> ▶ Based on generic aquatic and terrestrial ecosystems assumed to be near source category facilities ▶ HAPs screened for those that might require multipathway analyses ▶ Generic multimedia conceptual model simplified based on HAP characteristics and likely exposure pathways ▶ Generic assessment endpoints of maintaining ecological community structure and function are used for the communities that might be exposed 	<ul style="list-style-type: none"> ▶ Based on more site-specific information on ecosystems, habitats, and species near the facilities of concern ▶ Results of screening analysis or other information used to identify HAPs and exposure pathways of concern ▶ More site-specific conceptual model developed based on results of screening analysis or other information and site-specific data ▶ Correspondingly more refined assessment endpoints are developed
Analysis Phase	<ul style="list-style-type: none"> ▶ Simple conservative assumptions and screening-level exposure models are used ▶ Conservative values from the literature are assumed for factors such as bioavailability and bioaccumulation ▶ Locations with maximum estimated HAP concentration are used to estimate exposure ▶ Screening-level ecotoxicity benchmarks are identified or developed as point estimates of no-observed-effect levels for the most sensitive species in the generic communities 	<ul style="list-style-type: none"> ▶ More refined assumptions, site-specific data, and refined exposure models are used ▶ More representative values from the literature or actual measurements from the field are used for factors such as bioavailability and bioaccumulation ▶ Spatial and temporal extent and magnitude of contamination are estimated ▶ Refined ecotoxicity benchmarks are identified or developed as point estimates of low-observed-effect levels for the assessment endpoints identified under problem formulation ▶ As data permit, full stressor-response curves might be developed ▶ Actual field evaluation of ecological condition near some facilities might be performed
Criteria	<ul style="list-style-type: none"> ▶ HI <1 acceptable; ≥ 1 leads to a reexamination of conservative assumptions and, if the HI continues to exceed 1, to a more refined analysis ▶ Consideration of potential environmental significance of effects limited to benchmark selection and prioritization 	<ul style="list-style-type: none"> ▶ HI <1 acceptable; ≥ 1 may be acceptable depending on ecological significance ▶ Potential environmental significance of effects is evaluated based on a number of factors, including areal extent and magnitude of estimated effects on assessment endpoints and local, State, Tribal, regional, or national significance of the assessment endpoints

^aRefined assessment based on more detailed and site-specific, and less conservative, estimated HAP exposures at the MIR location and throughout the spatial area of impact. EPA consensus toxicity values, or equivalent, reviewed in light of any additional credible and relevant information, are typically used.

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At the end of the screening-level risk characterization, if none of the estimated environmental concentrations are greater than the corresponding criteria, the conservative risk screen indicates that the source category does not pose a risk of "an adverse environmental effect." The results of the screening analysis should be documented, and the ecological risk assessment process would stop. On the other hand, there might be one or more HAPs and combinations of exposure media and ecological communities for which the exposure concentration is greater than the screening ecotoxicity criteria (i.e., the hazard quotient is greater than 1) or for which the sum of the hazard quotients that apply to the same communities exceeds 1. If any sources or HAPs result in exposures in excess of the appropriate ecotoxicity screening criteria, further analysis may be warranted.

If estimated levels are only slightly greater than screening-level ecotoxicity criteria (e.g., less than an order of magnitude), it is worth reexamining all of the conservative assumptions used in the screening analyses to see if a more realistic combination of fate and transport parameters or more realistic values for other key parameters would change the result. Common conservative assumptions that should be reexamined at this point include, among others, use of conservative bioaccumulation factors from the literature, assuming that bioavailability is 100 percent, or assuming that 100 percent of a metal is present in its most toxic form (e.g., methyl mercury instead of elemental mercury). The basis for the criteria may also be reexamined at this point with regard to underlying uncertainties.

If estimated environmental concentrations are substantially greater than screening-level ecotoxicity criteria (e.g., more than an order of magnitude) and remain so after selected less conservative assumptions are used, then a more refined risk assessment may be indicated. If only one or a few of the facilities within a source category are likely to be causing the result, then a more refined assessment for those individual facilities using site-specific information might be appropriate. If several facilities are likely to be at issue, a more refined analysis for the source category might be needed.

5.3.5 Refined Analyses

For source categories that proceed from screening to refined risk assessments, additional data collection will be required, with a greater emphasis on site-specific data for affected facilities. As mentioned previously, some assessments may begin at the refined level. In some cases, this data collection effort may be relatively extensive, although it should be able to be focused based on the results of the screening assessment, when done, on the HAPs, types of effects (i.e., endpoints), sources, locations, exposure pathways, and receptors of most concern. Data collection to support the refined assessment may involve more detail about data elements used in the screening assessment (e.g., HAP emission rates, source characteristics) as well as information about additional data elements (e.g., exposed populations and subpopulations, epidemiology and disease registry information, actual ecosystems and endangered and threatened species that might be exposed). This data collection step is also more likely to include collection